

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
FRANKFORT DIVISION**

**CITY OF HENDERSON, KENTUCKY,
ON BEHALF OF THEMSELVES AND
ALL OTHER SIMILARLY SITUATED
HOME RULE CITIES,**

PLAINTIFFS,

v.

PURDUE PHARMA L.P., ET AL.,

DEFENDANTS.

No. 3:19-cv-00067-GFV

MOTION TO REMAND

Plaintiff, on behalf of itself and the Putative Class, (collectively the “Kentucky Home Rule City Class”), hereby move the Court to remand their complaint to Franklin Circuit Court.

The Kentucky Home Rule City Class submits that Defendant Beverly Sackler’s (“Sackler”) notice of removal based solely on the Class Action Fairness Act (“CAFA”) fails to demonstrate—and makes no effort to demonstrate—that the required jurisdiction requirement of at least 100 putative class members is met and, as such, requires remand. Moreover, even were the numerosity requirement present, remand would be warranted based on the Local Controversy exception—thereby allowing the Kentucky Home Rule City Class to pursue their state law claims against Kentucky defendants for actions and resulting damages in Kentucky.

The Kentucky Home Rule City Class also submits that Defendant McKesson Corp.’s (“McKesson”) supplemental removal notice based on federal question jurisdiction is flawed and requires remand. First, as a dispositive procedural requirement, McKesson’s notice is not supported by all of the defendants. Absent the required statutory unanimity, the removal is

procedurally deficient, and remand mandated. Second, as to the merits of its federal question allegations, the courts have consistently rejected McKesson's reliance on this same argument. Again, remand is warranted.

As further discussed herein, the Kentucky Home Rule City Class respectfully requests the Court grant their motion and remand their state law claims to Franklin Circuit Court without further delay.

Discussion

A. The elements necessary for CAFA jurisdiction are missing and remand is warranted.

Sackler removed the Kentucky Home Rule City Class' claims based solely on CAFA jurisdiction. *See* Dkt. 1: Removal Notice, p.2. As addressed in the following discussion, the removal notice has failed to satisfy a required element necessary for the Court to exercise CAFA jurisdiction—a minimum of 100 putative class members. Furthermore, and even if the jurisdictional numerosity requirement were satisfied, remand would be warranted based on the Local Controversy exception.

1. 28 U.S.C. § 1332(5)(B)—the *lack* of 100 putative class members—requires remand.

Just as diversity jurisdiction requires the removing party to demonstrate both diversity of citizenship and the amount in controversy,¹ CAFA requires the removing party to demonstrate minimal diversity,² greater than \$5,000,000 in controversy, and a proposed class size of at least 100 members—the numerosity requirement.

(5) Paragraphs (2) through (4) shall *not* apply to any class action in which—

¹ *See* 28 U.S.C. § 1332(a).

² *See* 28 U.S.C. § 1332(d)(2).

* * * * *

- (B) the number of members of all proposed plaintiff classes in the aggregate is ***less than 100***.

29 U.S.C. § 1332(d)(5)(B) (emph. added).

Again, Sackler removed this action based solely on CAFA jurisdiction. *See* Dkt. 1: Removal Notice, p.2. As the removing party, Sackler had the burden of demonstrating, by a preponderance of the evidence, that each of the requisite jurisdictional elements were satisfied—including the numerosity requirement.

But under CAFA, federal courts may hear class actions with minimal diversity, such that only one plaintiff and one defendant need be citizens of different States, ***so long as there are 100 or more class members*** and an aggregate amount in controversy of at least \$5,000,000.... As always, the ***removing*** defendant ***bears the burden*** of establishing federal court jurisdiction.

Roberts v. Mars Petcare US, Inc., 874 F.3d 953, 955 (6th Cir. 2017) (emph. added in part, internal cites omitted). Sackler failed to demonstrate this jurisdictional element was met.

Aside from summarily stating that there are “hundreds of Home Rule cities in the Commonwealth of Kentucky”, Sackler failed to identify or to provide any evidence as to how many of the alleged “hundreds” would fall within the putative class. Instead, Sackler chided the Kentucky Home Rule City Class for not pleading the issue. Dkt. 1, Removal Notice, p.3 (“Plaintiffs do not plead that more than twenty of them...”).³ Suffice to say, Sackler’s argument is misplaced. Sackler, not the Kentucky Home Rule City Class, bears the burden of persuasion when removing a state lawsuit solely involving state plaintiffs and solely asserting state law claims. *See supra*; *Mason v. Lockwood, Andrews & Newnam, P.C.*, 842 F.3d 383, 389 (6th Cir.

³ Sackler also fails to acknowledge paragraph 45 of the Complaint, in which the Kentucky Home Rule City Class clearly pleads that the “class is comprised of *less than* 100 Kentucky Home Rule cities”. *See* Dkt. 1-1, pp.10-11 (emph. original); *see also*, p.153 (The Plaintiff Class ... is less than one hundred (100)).

2016) (“[N]othing in CAFA alters the traditional rule that the *removing party bears the burden* of establishing the jurisdictional elements.”) (emph. added).

Again, the Kentucky Home Rule City Class was defined as follows:

All Kentucky Home Rule cities, with populations in excess of 4,000 and excluding those that have filed, and have pending, a civil action in the National Prescription Opiate Litigation MDL 2804.

Dkt. 1-1: Complaint, p.153 (emph. original). Despite acknowledging that the putative class expressly “excluded” those Kentucky Home Rule Cities (with populations in excess of 4,000) that had filed and had a pending action in the MDL, Sackler offered no evidence to demonstrate how many Kentucky Home Rule Cities were presently in the MDL and therefore excluded from the putative class. This failure alone defeats removal based on CAFA. However, despite Sackler’s failure to satisfy the jurisdictional numerosity requirement, as demonstrated by the attached exhibit there were only ninety (90) Home Rule cities with populations in excess of 4,000. *See* Exhibit A: Home Rule Cities.⁴ Any Home Rule Cities with pending actions in the MDL would only further reduce this number. Therefore, it is a factual impossibility for the Kentucky Home Rule City Class to ever equal or exceed the 100 member jurisdictional requirement.

Finally, without any legal citation or discussion, Sacker summarily concludes that a separate class action involving Kentucky Counties (Fiscal Courts) should be included when determining the 100 minimum class member jurisdictional requirement. *See* Dkt. 1: Notice, p.4. Even if the argument had merit, Sackler has provided no supporting evidence concerning the number of Kentucky Counties—a wholly different class of plaintiffs—that would ostensibly be part of any such extended class. *Id.* But there is no need to address Sackler’s lack of evidentiary

⁴ *See also*, <https://www.klc.org/InfoCentral/Detail/2/classification>.

support. The Sixth Circuit has previously addressed this very issue and rejected a similar argument. *See Freeman v. Blue Ridge Paper Prods.*, 551 F.3d 405 (6th Cir. 2008).

Freeman was a class action involving nuisance claims arising from a paper mill’s pollution of the local water supply. *Id.* at 406. A separate class action complaint was filed for the *same* plaintiffs, but with a “series of different, sequential six-month periods.” *Id.* On review, the Sixth Circuit reversed the district court’s remand of the class complaints that involved “identical parties and claims.” *Id.* However, the Sixth Circuit expressly recognized and acknowledged that its holding was “limited to the situation where there is no colorable basis for dividing up the sought-for retrospective relief into separate time periods.” *Id.* at 409.

When viewed in the context of the present case, there are *not* identical parties. The Kentucky counties and the home rule cities are wholly separate and distinct governmental entities. The two actions do *not* seek to divide up the same claim, involving the same parties, over multiple time periods. Rather, they are quite simply separate actions as evidenced by their respective filings and, importantly, their putative class definitions—each specifically drafted to support their respective certification with corresponding similarly situated lead plaintiffs. Just as it would be improper for a Home Rule City to assert claims on behalf of, or seek to represent the interests of, a different governmentally structured and administered entity—a Fiscal Court—so to would be the converse.

The Kentucky Home Rule City Class properly seeks to represent Kentucky cities—nothing more and nothing less—and has presented a colorable basis for so doing. Any aggregation of a wholly separate and distinct set of plaintiffs would be improper and contrary to *Freeman*. The Kentucky Home Rule City Class has pleaded their complaint both in accordance with Kentucky’s rules of civil procedure—not in response to any prior removal efforts as in

Freeman—and in accordance with their right as the “master of [their] complaint.” *See Smith v. Nationwide Prop. & Cas. Ins. Co.*, 505 F.3d 401, 407 (6th Cir. 2007).

2. 28 U.S.C. § 1332(d)(4)(A)—the Local Controversy exception—also requires remand.

CAFA, while allowing the removal to federal court of class-action cases involving non-diverse parties, contains several limitations on the exercise of federal jurisdiction. In particular, CAFA contains the “Local Controversy Exception.” *See* 28 U.S.C. § 1332(d)(4)(A). Under this exception, “[a] district court ***shall decline*** to exercise jurisdiction . . . over a class action” if:

- (i) (I) greater than two-thirds of the members of all proposed plaintiff classes in the aggregate are citizens of the State in which the action was originally filed;
- (II) at least 1 defendant is a defendant--
 - (aa) from whom significant relief is sought by members of the plaintiff class;
 - (bb) whose alleged conduct forms a significant basis for the claims asserted by the proposed plaintiff class; and
 - (cc) who is a citizen of the State in which the action was originally filed; and
- (III) principal injuries resulting from the alleged conduct or any related conduct of each defendant were incurred in the State in which the action was originally filed; and
- (ii) during the 3-year period preceding the filing of that class action, no other class action has been filed asserting the same or similar factual allegations against any of the defendants on behalf of the same or other persons[.]

Id. (emph. added); *Mason*, 842 F.3d at 386-87. “If these four elements are present, the district court ***must abstain*** from hearing the case, despite having jurisdiction under § 1332(d)(2).” *Id.* at 387 (emph. added).

The Local Controversy exception is applicable to the Kentucky Home Rule City Class’

claims. To begin, the roughly ninety (90) Home Rule Cities potentially encompassed within the putative class are indisputably citizens of the Commonwealth of Kentucky in which they filed the present action—readily satisfying the “two-thirds” requirement.

Second, the local defendant requirement is similarly satisfied. Not including the governmental defendants,⁵ at least two defendants are citizens of Kentucky. Both Rite Aid of Kentucky, Inc. and Kentucky CVS LLC are incorporated within the Commonwealth—the first as a corporation and the latter as an LLC.⁶ Each of these pharmacy defendants were substantially involved in the sale and distribution of opioids throughout the Commonwealth—serving as the last gate-keeping bastion between the end-user and access to the opioids. As such, the Kentucky Home Rule City Class seeks significant relief from both of these defendants for their conduct within and throughout the Commonwealth.

Third, and consistent with the first element, the Kentucky Home Rule City Class’ damages arose from, were caused by, and are directly attributable to the each of the foregoing pharmacy defendants’ actions and conduct within the Commonwealth. *See e.g.* KRS 315.022 (“The practice of pharmacy within the Commonwealth is declared to be a professional practice affecting the public health, safety, and welfare, and is subject to regulation and control in the public interest.”).

Finally, during the prior three (3) year period, there has not been a class action filed by,

⁵ The Kentucky Home Rule City Class also seeks significant relief from the Commonwealth of Kentucky, including its agents and agencies.

⁶ *See* [https://app.sos.ky.gov/ftshow/\(S\(k3gkvu15t3th3cnah2p5cjni\)\)/default.aspx?path=ftsearch&id=0084428&ct=09&cs=99999&ce=mqoll7lSKJ4qdqiSFPCymwPdMudKdFX1wNN A2o81982MAo0fWP0yu%2bvBxPtvwjMq](https://app.sos.ky.gov/ftshow/(S(k3gkvu15t3th3cnah2p5cjni))/default.aspx?path=ftsearch&id=0084428&ct=09&cs=99999&ce=mqoll7lSKJ4qdqiSFPCymwPdMudKdFX1wNN A2o81982MAo0fWP0yu%2bvBxPtvwjMq); [https://app.sos.ky.gov/ftshow/\(S\(gxrzy3bnng5haxr02shcotig\)\)/default.aspx?path=ftsearch&id=0631595&ct=06&cs=99999&ce=DhqT6YSrS4LUpACc2aFGKFRmRERWvTuHwjLzYWV9zltA5gBhvfH2RdT0LZMZP7K](https://app.sos.ky.gov/ftshow/(S(gxrzy3bnng5haxr02shcotig))/default.aspx?path=ftsearch&id=0631595&ct=06&cs=99999&ce=DhqT6YSrS4LUpACc2aFGKFRmRERWvTuHwjLzYWV9zltA5gBhvfH2RdT0LZMZP7K). (Oct. 28, 2019).

or on behalf, of the Kentucky Home Rule City Class against the same defendants or involving similar factual allegations. While there have been numerous lawsuits filed on behalf of county and city governments, both in state courts and in the current MDL, the lawsuits were filed in their individual capacity only.

“The local controversy exception exists to ensure that ‘a truly local controversy—a controversy that uniquely affects a particular locality to the exclusion of all others’—remains in state court.” *Mason*, 842 F.3d at 397. The plaintiffs are comprised solely of Kentucky governmental entities—Home Rule Cities—pursuing their police and regulatory powers to address the local impact of the defendants’ collective, and individual, actions within the Commonwealth of Kentucky. As with the *Mason* case, the Kentucky Home Rule City Class’ claims exemplify the “quintessential local controversy.” *Id.* (“[I]t defies common sense to say a suit by Flint residents against those purportedly responsible for injuring them through their municipal water service is not a ‘local controversy.’”). Therefore, the “Local Controversy Exception” requires remand of the Kentucky Home Rule City Class’ claims.

B. Federal Question jurisdiction is similarly missing also requiring remand.

As previously noted, on October 24, 2019, Defendant McKesson Corp. filed a *Supplemental Notice of Removal*. See Dkt. 82. The removal notice incorporated without modification Sackler’s removal based on CAFA. The notice also asserted federal question jurisdiction. *Id.* at p.7, citing 28 U.S.C. §§ 1441 and 1331. Just as with Sackler’s CAFA removal, McKesson’s federal question removal is both procedurally and substantively flawed—meriting remand.

1. McKesson’s decision to remove the case with the express consent of all defendants was procedurally improper and independently warrants remand.

As a threshold procedural issue, even if jurisdictional issues were not fatal to the removal,

see supra, McKesson’s decision to remove the case without the express consent of **all** defendants was procedurally improper and independently warrants remand—failure to satisfy the rule of unanimity. The unanimity requirement is expressly required by statute.

When a civil action is removed solely under section 1441(a), **all defendants** who have been properly joined and served **must join** in or consent to the removal of the action.

29 U.S.C. § 1446(b)(2)(A) (emph. added); *Loftis v. UPS*, 342 F.3d 509, 516 (6th Cir. 2003) (“This rule of unanimity demands that all defendants must join in a petition to remove a state case to federal court.”). “Failure to obtain unanimous consent forecloses the opportunity for removal under Section 1446.” *Id.*

McKesson clearly recognized the unanimity procedural requirement and actively sought to obtain consent from some but not all of the other defendants. In particular, McKesson admittedly failed to obtain and provide any evidence that Defendant West-Ward Pharmaceuticals Corp. n/k/a Hikma Pharmaceuticals, plc consented to the removal. *See* Dkt. 82: Supp. Notice, p.20. Instead, and without any evidentiary support, McKesson summarily claimed that West-Ward had “not been served.” *Id.* McKesson’s speculation is misplaced. West-Ward **was served** on September 23, 2019—the day before McKesson was admittedly served. *See* Drake Declaration; Exhibit B. To the extent West-Ward was going to remove, or join in any removal action, it was required to do so on or before October 24, 2019. For reasons known only to it, West-Ward declined to attempt to invoke federal jurisdiction and is foreclosed from doing so now. As a result, absent West-Ward’s consent, McKesson’s removal notice is fatally defective, and remand is warranted.

Finally, McKesson has also failed to demonstrate the Kentucky State Defendants agreed to waive their 11th Amendment protections and to join in the removal of this action. Instead, McKesson summarily states the Kentucky State Defendants are aligned with the Kentucky Home

Rule City Class' claims. This argument is misleading, if not disingenuous. The Kentucky Home Rule City Class have asserted claims **against** the Kentucky State defendants for their respective failures to fulfill their Kentucky statutory duties. There is no alignment as to these claims, and as such, the Kentucky Home Rule City Class seeks appropriate relief under Kentucky law and against the Kentucky State Defendants. Again, the unanimity requirement is not and cannot be satisfied.

2. The Kentucky Home Rule City Class claims do *not* raise a federal question.

The removal statute, 28 U.S.C. § 1441, provides that “any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants.” As already noted, McKesson contends the court has original jurisdiction over this action because it presents a federal question. *See* Dkt 82. However, in reviewing the merits of McKesson’s removal, it is worth noting that federal courts are courts of **limited** jurisdiction, possessing only that power authorized by Constitution and statute. There generally exists a presumption that a cause lies outside this limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction. Under these principles, McKesson bears the burden to show the propriety of removal by establishing that this court enjoys subject federal question jurisdiction over the action—strictly construed against removal. *See Shamrock Oil & Gas Corp. v. Sheets*, 313 U.S. 100, 108-09 (1941); *Coyne v. Am. Tobacco Co.*, 183 F.3d 488, 493 (6th Cir. 1999).

A review of the pleadings, and the litany of federal cases directly on point, supports the court finding McKesson has **not** carried its burden necessary to undermine the fact that the Kentucky Home Rule City Class claims arise solely under Kentucky law and should be resolved by Kentucky courts. The complaint expressly states the Kentucky Home Rule City Class does **not** seek any relief based on, or assert any claims under, federal law.

This action is not removable to federal court for many reasons, including inter alia ... (ii) the claims asserted herein arise solely under Kentucky’s laws and regulations; (iii) no claims are asserted under any federal law or regulation, and any inference to the contrary is expressly disavowed...

Dkt 1-1: Complaint, p.10 (emph. original). While the complaint makes a factual reference to a federal database (the “CSA”) and corresponding reporting requirement, this is a fact—not a claim. Nor does the CSA reference require recasting of the Kentucky Home Rule City Class’ state law claims under federal law or divest the Kentucky courts of their Constitutionally protected regulatory and judicial authority. The Kentucky Home Rule City Class’ state law claims do **not** require proof of a federal claim in order to obtain relief.

Moreover, as McKesson is well aware, “the presence of a presence of a claimed violation of the statute as an element of a state cause of action **is insufficiently substantial to confer federal-question** jurisdiction.” *See Weber Cnty. v. Purdue Pharma, L.P.*, 2018 U.S. Dist. LEXIS 133312, at *11 (D. Utah Aug. 7, 2018) (quoting *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 816 (1986)) (emph. added). Moreover, the federal courts to have considered McKesson’s argument have rejected finding federal question jurisdiction.

The allegations in Weber County’s Complaint undoubtedly reference federal laws and some Defendants’ breaches of those laws. But Weber County **asserts only state law claims** and provides bases for the claims which **do not arise out of or necessarily depend on an interpretation of a disputed CSA** provision. Under these circumstances, the Complaint does not necessarily raise federal issues.

Weber Cnty., 2018 U.S. Dist. LEXIS 133312, at *14-15 (emph. added); *see also, Uintah Cnty. v. Purdue Pharma, L.P.*, 2018 U.S. Dist. LEXIS 133310, at *24 (D. Utah Aug. 7, 2018) (same).

The first factor weighs against federal question jurisdiction because the CSA does **not** provide for a federal cause of action.

* * * * *

The second factor also weighs against federal question jurisdiction. ... McKesson has not persuaded this Court that the state court will have to make any inquiry regarding the scope and existence of the duties imposed by the CSA because Reno could prevail on its claims based on the duties imposed by NAC § 453.400 alone....

* * * * *

The third factor—whether the issue will have a broad impact on the federal system as a whole—also is not satisfied here. The issue before the state court will be whether McKesson and others breached the duties imposed by Nevada law, including NAC § 453.400.

City of Reno v. Purdue Pharma, L.P., 2018 U.S. Dist. LEXIS 187821, at *8-9 (D. Nev. Nov. 2, 2018) (emph. added, internal citations omitted); *see also*, *N.M. ex rel. Balderas v. Purdue Pharma L.P.*, 323 F.Supp.3d 1242, 1253 (D.N.M. 2018) (finding federal question jurisdiction did not apply); *Cnty. of Kern v. Purdue Pharma L.P.*, 2019 U.S. Dist. LEXIS 122709, at *7-8 (E.D. Cal. July 23, 2019); *City of Worcester v. Purdue Pharma Ltd. P’ship*, 2018 U.S. Dist. LEXIS 215824, at *10 (D. Mass. Nov. 21, 2018) (collecting cases).

More recently, district courts in the Sixth Circuit had addressed and rejected similar arguments seeking to create a federal question based on a factual reference to the CSA. In *Dunaway v. Purdue Pharma L.P.*, the court found that despite the complaint’s reference to the CSA, a federal issue was not “necessarily raised” or “substantial.” 391 F.Supp.3d 802, 813 (M.D. Tenn. 2019). As with the Kentucky Home Rule City Class’ claims, the Tennessee court recognized that the plaintiffs had alleged an array of overlapping state law claims that would likely subsume any reliance on the CSA. *Id.*

Numerous other opioid-related cases involving purely state-law prohibitions have been remanded for similar reasons as those presented by the plaintiffs.... As those courts have recognized, the fact that opioid abuse is an issue of national importance that is addressed, to some degree, by federal law ***in no way undermines the power of states to craft independent responses*** that do not rely on federal law to impose liability. When a state has done so—as

Tennessee has done here (by the plaintiffs' theory of the case)—then ***the appropriate forum for such causes of action are state courts***, unless a filing or removing party can establish a recognized basis for federal jurisdiction. Because McKesson has not done so, this court will remand the case.

Id. at 813-814 (collecting cases supporting remand) (emph. added).

The MDL Court has also weighed in and rejected the argument that a factual reference to the CSA can support federal question jurisdiction. *In re Nat'l Prescription Opiate Litig.*, 2019 U.S. Dist. LEXIS 6425, at *65 (N.D. Ohio Jan. 14, 2019). In addressing the Commonwealth of Kentucky's state law claims against Walgreens, the MDL Court recognized that—as with the Kentucky Home Rule City Class—the Commonwealth did *not* facially assert federal claims. *Id.* Moreover, as to the merits of Walgreen's arguments based on the CSA—the same arguments raised by McKesson, the MDL Court determined Walgreens had not and could not meet its burden.

District Courts examining virtually identical facts to those present here have determined that:

While a determination of a duty and violation of that duty under the FCSA will likely occur in examining Plaintiff's claims, so also will examination of [state] common law, statutes, and promulgated rules to determine Defendants' duty, if any, to prevent "diversion" of prescription drugs into illicit channels. And to the extent, if any, that Plaintiff's claims are "partially predicated on federal law, federal law would still not be necessarily raised."

Walgreens cannot meet its burden of showing that removal of Kentucky's case was proper under either the well-pleaded complaint rule or the Grable test. Therefore, this Court does not have jurisdiction over Kentucky's claims.

Id. at *65-66 (also collecting cases).

The Kentucky Home Rule City Class' claims are based solely on Kentucky law and the defendants'—including McKesson's—corresponding duties. Absent a federal question, remand is warranted and required.

Conclusion

Based on the foregoing, Plaintiffs, on behalf of themselves and the Putative Class, respectfully request the Court grant their motion and remand their complaint to Kentucky State Court. A proposed order is attached for the Court's consideration.

* * * * *

Dated: October 28, 2019

s/ Andrew M. Grabhorn

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Counsel for Plaintiffs City of Henderson, Kentucky and the Putative Class

	A	B	C	D	E	F	G
1	City Name	Class as of January 1, 2014	Class as of August 1, 2014	Class as of January 1, 2015	2010 Pop. Census	2015 Pop. Est.	County
2	Louisville	1	1	First	597,337	615,366	Jefferson
3	Lexington	2	2	Home Rule	295,803	314,488	Fayette
4	Bowling Green	2	2	Home Rule	58,067	63,616	Warren
5	Owensboro	2	2	Home Rule	57,265	59,042	Daviess
6	Covington	2	2	Home Rule	40,640	40,997	Kenton
7	Richmond	2	2	Home Rule	31,364	33,533	Madison
8	Georgetown	4	4	Home Rule	29,098	32,356	Scott
9	Florence	3	3	Home Rule	29,951	32,227	Boone
10	Hopkinsville	2	2	Home Rule	31,577	32,205	Christian
11	Nicholasville	3	3	Home Rule	28,015	29,754	Jessamine
12	Elizabethtown	4	4	Home Rule	28,531	29,678	Hardin
13	Henderson	2	2	Home Rule	28,757	28,890	Henderson
14	Frankfort	2	2	Home Rule	25,527	27,830	Franklin
15	Jeffersontown	2	2	Home Rule	26,595	26,946	Jefferson
16	Independence	3	3	Home Rule	24,757	26,819	Kenton
17	Paducah	2	2	Home Rule	25,024	24,864	McCracken
18	Radcliff	2	2	Home Rule	21,692	22,387	Hardin
19	Ashland	2	2	Home Rule	21,684	21,108	Boyd
20	Madisonville	4	4	Home Rule	19,591	19,539	Hopkins
21	Murray	3	3	Home Rule	17,741	18,954	Calloway
22	Erlanger	3	3	Home Rule	18,082	18,797	Kenton
23	Winchester	3	3	Home Rule	18,368	18,446	Clark
24	Saint Matthews	4	4	Home Rule	17,472	18,025	Jefferson
25	Danville	3	3	Home Rule	16,218	16,690	Boyle
26	Fort Thomas	4	4	Home Rule	16,325	16,398	Campbell
27	Shively	3	3	Home Rule	15,264	15,713	Jefferson
28	Newport	2	2	Home Rule	15,273	15,354	Campbell
29	Shelbyville	4	4	Home Rule	14,045	15,253	Shelby
30	Berea	4	4	Home Rule	13,561	14,882	Madison
31	Glasgow	3	3	Home Rule	14,028	14,470	Barren
32	Mount Washington	4	4	Home Rule	9,117	14,028	Bullitt
33	Bardstown	4	4	Home Rule	11,700	13,091	Nelson
34	Shepherdsville	4	4	Home Rule	11,222	11,967	Bullitt
35	Somerset	3	3	Home Rule	11,196	11,439	Pulaski
36	Lyndon	4	4	Home Rule	11,002	11,372	Jefferson
37	Campbellsville	3	3	Home Rule	9,108	11,237	Taylor
38	Lawrenceburg	4	4	Home Rule	10,505	11,103	Anderson
39	Mayfield	3	3	Home Rule	10,024	10,080	Graves
40	Paris	3	3	Home Rule	8,553	9,870	Bourbon
41	Middlesborough	3	3	Home Rule	10,334	9,710	Bell
42	Versailles	4	4	Home Rule	8,568	9,146	Woodford
43	Alexandria	4	4	Home Rule	8,477	9,009	Campbell
44	Maysville	3	3	Home Rule	9,011	8,819	Mason
45	Franklin	4	4	Home Rule	8,408	8,787	Simpson
46	Edgewood	4	4	Home Rule	8,575	8,769	Kenton
47	LaGrange	4	4	Home Rule	8,082	8,619	Oldham
48	Elsmere	4	4	Home Rule	8,451	8,536	Kenton
49	Harrodsburg	4	4	Home Rule	8,340	8,394	Mercer
50	Fort Mitchell	4	4	Home Rule	8,207	8,306	Kenton
51	London	4	4	Home Rule	7,993	8,126	Laurel

	A	B	C	D	E	F	G
1	City Name	Class as of January 1, 2014	Class as of August 1, 2014	Class as of January 1, 2015	2010 Pop. Census	2015 Pop. Est.	County
52	Hillview	4	4	Home Rule	8,172	8,080	Bullitt
53	Middletown	4	4	Home Rule	7,218	7,874	Jefferson
54	Villa Hills	4	4	Home Rule	7,489	7,468	Kenton
55	Oak Grove	4	4	Home Rule	7,489	7,444	Christian
56	Corbin	4	4	Home Rule	7,304	7,389	Whitley/Knox
57	Flatwoods	3	3	Home Rule	7,423	7,335	Greenup
58	Mount Sterling	4	4	Home Rule	6,895	7,208	Montgomery
59	Highland Heights	4	4	Home Rule	6,923	7,183	Campbell
60	Russellville	4	4	Home Rule	6,960	7,056	Logan
61	Morehead	4	4	Home Rule	6,845	7,045	Rowan
62	Pikeville	4	4	Home Rule	6,903	7,012	Pike
63	Leitchfield	4	4	Home Rule	6,699	6,873	Grayson
64	Taylor Mill	4	4	Home Rule	6,604	6,769	Kenton
65	Cynthiana	4	4	Home Rule	6,402	6,423	Harrison
66	Wilmore	4	4	Home Rule	3,686	6,247	Jessamine
67	Princeton	4	4	Home Rule	6,329	6,174	Caldwell
68	Cold Spring	5	5	Home Rule	5,912	6,170	Campbell
69	Monticello	4	4	Home Rule	6,188	6,090	Wayne
70	Bellevue	4	4	Home Rule	5,955	5,892	Campbell
71	Central City	4	4	Home Rule	5,978	5,892	Muhlenberg
72	Union	4	4	Home Rule	5,379	5,795	Boone
73	Fort Wright	4	4	Home Rule	5,723	5,781	Kenton
74	Vine Grove	4	4	Home Rule	4,520	5,760	Hardin
75	Lebanon	4	4	Home Rule	5,539	5,680	Marion
76	Douglass Hills	4	4	Home Rule	5,484	5,669	Jefferson
77	Dayton	4	4	Home Rule	5,338	5,433	Campbell
78	Hazard	3	3	Home Rule	4,456	5,341	Perry
79	Williamsburg	4	4	Home Rule	5,245	5,293	Whitley
80	Prospect	3	3	Home Rule	4,698	4,881	Jefferson/Oldham
81	Crestwood	5	4	Home Rule	4,531	4,847	Oldham
82	Columbia	4	4	Home Rule	4,452	4,644	Adair
83	Ludlow	4	4	Home Rule	4,407	4,551	Kenton
84	Scottsville	4	4	Home Rule	4,226	4,411	Allen
85	Greenville	4	4	Home Rule	4,312	4,395	Muhlenberg
86	Hurstbourne	4	4	Home Rule	4,216	4,359	Jefferson
87	Benton	4	4	Home Rule	4,349	4,357	Marshall
88	Paintsville	4	4	Home Rule	3,459	4,249	Johnson
89	Grayson	4	4	Home Rule	4,217	4,058	Carter
90	Crescent Springs	4	4	Home Rule	3,801	4,010	Kenton
91	Williamstown	5	4	Home Rule	3,925	3,943	Grant/Pendleton
92	Walton	5	5	Home Rule	3,635	3,907	Boone/Kenton
93	Carrollton	4	4	Home Rule	3,938	3,886	Carroll
94	Lancaster	4	4	Home Rule	3,442	3,864	Garrard
95	Southgate	4	4	Home Rule	3,803	3,856	Campbell
96	Crittenden	5	5	Home Rule	3,815	3,848	Grant
97	Stanford	4	4	Home Rule	3,487	3,675	Lincoln
98	Beaver Dam	4	4	Home Rule	3,409	3,618	Ohio
99	Morganfield	4	4	Home Rule	3,285	3,578	Union
100	Prestonsburg	4	4	Home Rule	3,255	3,347	Floyd
101	Crestview Hills	4	4	Home Rule	3,148	3,340	Kenton

	A	B	C	D	E	F	G
1	City Name	Class as of January 1, 2014	Class as of August 1, 2014	Class as of January 1, 2015	2010 Pop. Census	2015 Pop. Est.	County
102	West Liberty	4	4	Home Rule	3,435	3,330	Morgan
103	Russell	4	4	Home Rule	3,380	3,260	Greenup
104	Hodgenville	4	4	Home Rule	3,206	3,256	Larue
105	Barbourville	4	4	Home Rule	3,165	3,174	Knox
106	Wilder	5	5	Home Rule	3,035	3,088	Campbell
107	Providence	4	4	Home Rule	3,193	3,065	Webster
108	Springfield	4	4	Home Rule	2,519	3,055	Washington
109	Park Hills	4	4	Home Rule	2,970	3,007	Kenton
110	Marion	4	4	Home Rule	3,039	2,986	Crittenden
111	Indian Hills	4	4	Home Rule	2,868	2,959	Jefferson
112	Graymoor-Devondale	4	4	Home Rule	2,870	2,950	Jefferson
113	Flemingsburg	4	4	Home Rule	2,658	2,894	Fleming
114	Brandenburg	5	5	Home Rule	2,643	2,852	Meade
115	Pioneer Village	4	4	Home Rule	2,030	2,840	Bullitt
116	Lakeside Park	5	5	Home Rule	2,668	2,779	Kenton
117	Hartford	5	5	Home Rule	2,672	2,750	Ohio
118	Dawson Springs	4	4	Home Rule	2,764	2,737	Hopkins/Caldwell
119	Simpsonville	5	5	Home Rule	2,484	2,702	Shelby
120	Stanton	4	4	Home Rule	2,733	2,666	Powell
121	Cadiz	4	4	Home Rule	2,558	2,626	Trigg
122	Eddyville	4	4	Home Rule	2,554	2,577	Lyon
123	Eminence	4	4	Home Rule	2,498	2,535	Henry
124	Calvert City	4	4	Home Rule	2,566	2,532	Marshall
125	Russell Springs	5	4	Home Rule	2,441	2,511	Russell
126	Mount Vernon	5	5	Home Rule	2,477	2,499	Rockcastle
127	Morgantown	5	5	Home Rule	2,394	2,475	Butler
128	Louisa	5	4	Home Rule	2,467	2,455	Lawrence
129	Windy Hills	5	5	Home Rule	2,385	2,428	Jefferson
130	Anchorage	4	4	Home Rule	2,348	2,420	Jefferson
131	Irvine	4	4	Home Rule	2,715	2,416	Estill
132	Cave City	4	4	Home Rule	2,240	2,394	Barren
133	Raceland	5	5	Home Rule	2,424	2,387	Greenup
134	Horse Cave	4	4	Home Rule	2,311	2,344	Hart
135	Hardinsburg	5	5	Home Rule	2,343	2,333	Breckinridge
136	Tompkinsville	5	5	Home Rule	2,402	2,289	Monroe
137	Junction City	4	4	Home Rule	2,241	2,283	Boyle/Lincoln
138	Fulton	4	4	Home Rule	2,445	2,235	Fulton
139	Dry Ridge	5	5	Home Rule	2,191	2,205	Grant
140	Hickman	4	4	Home Rule	2,395	2,202	Fulton
141	Elkton	4	4	Home Rule	2,062	2,175	Todd
142	Liberty	5	5	Home Rule	2,168	2,160	Casey
143	Jackson	4	4	Home Rule	2,231	2,152	Breathitt
144	Falmouth	4	4	Home Rule	2,169	2,127	Pendleton
145	Greensburg	4	4	Home Rule	2,163	2,123	Green
146	Cumberland	4	4	Home Rule	2,237	2,103	Harlan
147	Jenkins	4	4	Home Rule	2,203	2,103	Letcher
148	Albany	4	4	Home Rule	2,033	2,012	Clinton
149	Carlisle	4	4	Home Rule	2,010	2,010	Nicholas
150	Whitesburg	4	4	Home Rule	2,139	2,006	Letcher
151	Lebanon Junction	5	5	Home Rule	1,813	1,917	Bullitt

	A	B	C	D	E	F	G
1	City Name	Class as of January 1, 2014	Class as of August 1, 2014	Class as of January 1, 2015	2010 Pop. Census	2015 Pop. Est.	County
152	Sturgis	4	4	Home Rule	1,898	1,912	Union
153	Hurstbourne Acres	4	4	Home Rule	1,811	1,874	Jefferson
154	Salyersville	4	4	Home Rule	1,883	1,816	Magoffin
155	Catlettsburg	4	4	Home Rule	1,856	1,808	Boyd
156	Jamestown	5	5	Home Rule	1,794	1,804	Russell
157	Pineville	4	4	Home Rule	1,732	1,762	Bell
158	Orchard Grass Hills	5	5	Home Rule	1,595	1,711	Oldham
159	Jeffersonville	5	5	Home Rule	1,506	1,704	Montgomery
160	Midway	4	4	Home Rule	1,641	1,701	Woodford
161	Lewisport	5	5	Home Rule	1,670	1,698	Hancock
162	Warsaw	4	4	Home Rule	1,615	1,695	Gallatin
163	Munfordville	5	5	Home Rule	1,615	1,640	Hart
164	Harlan	4	4	Home Rule	1,745	1,639	Harlan
165	Coal Run Village	6	6	Home Rule	1,706	1,602	Pike
166	Olive Hill	4	4	Home Rule	1,599	1,599	Carter
167	Owingsville	4	4	Home Rule	1,530	1,581	Bath
168	Worthington	5	5	Home Rule	1,609	1,577	Greenup
169	Edmonton	5	5	Home Rule	1,595	1,568	Metcalfe
170	Sebree	5	5	Home Rule	1,603	1,559	Webster
171	Owenton	5	5	Home Rule	1,327	1,550	Owen
172	Pewee Valley	5	5	Home Rule	1,456	1,529	Oldham
173	Burkesville	5	5	Home Rule	1,521	1,515	Cumberland
174	Audubon Park	5	5	Home Rule	1,473	1,508	Jefferson
175	Saint Regis Park	4	4	Home Rule	1,454	1,504	Jefferson
176	Worthington Hills	6	6	Home Rule	1,446	1,496	Jefferson
177	Vanceburg	4	4	Home Rule	1,518	1,448	Lewis
178	Guthrie	4	4	Home Rule	1,419	1,437	Todd
179	Manchester	4	4	Home Rule	1,255	1,401	Clay
180	Earlington	4	4	Home Rule	1,413	1,395	Hopkins
181	Beechwood Village	5	5	Home Rule	1,324	1,365	Jefferson
182	Livermore	5	5	Home Rule	1,365	1,354	McLean
183	Auburn	5	5	Home Rule	1,340	1,352	Logan
184	Clinton	5	5	Home Rule	1,388	1,318	Hickman
185	West Buechel	5	5	Home Rule	1,230	1,269	Jefferson
186	Barbourmeade	5	5	Home Rule	1,218	1,258	Jefferson
187	Beattyville	5	5	Home Rule	1,307	1,244	Lee
188	Brodhead	5	5	Home Rule	1,211	1,205	Rockcastle
189	Nortonville	5	5	Home Rule	1,204	1,190	Hopkins
190	Irvington	5	5	Home Rule	1,181	1,184	Breckinridge
191	Augusta	4	4	Home Rule	1,190	1,163	Bracken
192	Greenup	5	5	Home Rule	1,188	1,157	Greenup
193	Cloverport	5	5	Home Rule	1,152	1,156	Breckinridge
194	Hebron Estates	5	5	Home Rule	1,087	1,145	Bullitt
195	Clay	5	5	Home Rule	1,181	1,141	Webster
196	Coldstream	6	6	Home Rule	1,100	1,137	Jefferson
197	Camargo	5	5	Home Rule	1,081	1,124	Montgomery
198	Silver Grove	5	5	Home Rule	1,102	1,120	Campbell
199	Heritage Creek	5	5	Home Rule	1,076	1,118	Jefferson
200	South Shore	5	5	Home Rule	1,122	1,101	Greenup
201	Clay City	5	5	Home Rule	1,077	1,095	Powell


	A	B	C	D	E	F	G
1	City Name	Class as of January 1, 2014	Class as of August 1, 2014	Class as of January 1, 2015	2010 Pop. Census	2015 Pop. Est.	County
202	Bloomfield	5	5	Home Rule	838	1,052	Nelson
203	Northfield	5	5	Home Rule	1,020	1,051	Jefferson
204	Wurtland	5	5	Home Rule	995	1,043	Greenup
205	Ryland Heights	5	5	Home Rule	1,022	1,042	Kenton
206	Taylorsville	4	4	Home Rule	763	1,028	Spencer
207	LaCenter	5	5	Home Rule	1,009	1,005	Ballard
208	Hawesville	5	5	Home Rule	945	1,002	Hancock
209	Watterson Park	5	5	Home Rule	976	1,001	Jefferson
210	Rolling Hills	5	5	Home Rule	959	991	Jefferson
211	Muldraugh	5	5	Home Rule	947	985	Hardin/Meade
212	Goshen	5	5	Home Rule	909	974	Oldham
213	Woodlawn Park	5	5	Home Rule	942	974	Jefferson
214	Langdon Place	6	6	Home Rule	936	969	Jefferson
215	Uniontown	5	5	Home Rule	1,002	967	Union
216	Burgin	5	5	Home Rule	965	965	Mercer
217	Ferguson	5	5	Home Rule	924	943	Pulaski
218	Lynnview	5	5	Home Rule	914	940	Jefferson
219	Elkhorn City	4	4	Home Rule	982	937	Pike
220	New Castle	5	5	Home Rule	912	926	Henry
221	Evarts	5	5	Home Rule	962	925	Harlan
222	Dixon	6	6	Home Rule	786	898	Webster
223	Clarkson	6	5	Home Rule	875	895	Grayson
224	Bellemeade	6	6	Home Rule	865	894	Jefferson
225	Adairville	5	5	Home Rule	852	889	Logan
226	Pembroke	5	5	Home Rule	869	889	Christian
227	New Haven	6	6	Home Rule	855	887	Nelson
228	White Plains	5	5	Home Rule	884	872	Hopkins
229	West Point	5	5	Home Rule	797	868	Hardin
230	Bellefonte	6	6	Home Rule	888	866	Greenup
231	Plantation	5	5	Home Rule	832	859	Jefferson
232	Mortons Gap	5	5	Home Rule	863	852	Hopkins
233	Fincastle	6	6	Home Rule	817	848	Jefferson
234	Pleasureville	6	6	Home Rule	834	844	Henry/Shelby
235	Burnside	4	4	Home Rule	611	843	Pulaski
236	Crab Orchard	6	6	Home Rule	841	833	Lincoln
237	Campbellsburg	5	5	Home Rule	813	828	Henry
238	Brownsville	5	5	Home Rule	836	826	Edmonson
239	Hollow Creek	5	5	Home Rule	783	810	Jefferson
240	Bromley	5	5	Home Rule	763	809	Kenton
241	Lewisburg	5	5	Home Rule	810	807	Logan
242	Millersburg	5	5	Home Rule	792	796	Bourbon/Nicholas
243	Blue Ridge Manor	6	6	Home Rule	767	794	Jefferson
244	McKee	5	5	Home Rule	800	789	Jackson
245	Calhoun	5	5	Home Rule	763	762	McLean
246	Perryville	5	5	Home Rule	751	761	Boyle
247	Meadow Vale	5	5	Home Rule	736	758	Jefferson
248	Crofton	5	5	Home Rule	749	754	Christian
249	Hindman	5	5	Home Rule	777	741	Knott
250	Green Spring	6	6	Home Rule	715	740	Jefferson
251	Salem	6	6	Home Rule	752	739	Livingston

	A	B	C	D	E	F	G
1	City Name	Class as of January 1, 2014	Class as of August 1, 2014	Class as of January 1, 2015	2010 Pop. Census	2015 Pop. Est.	County
252	Hanson	6	6	Home Rule	742	736	Hopkins
253	Smiths Grove	5	5	Home Rule	714	736	Warren
254	Powderly	5	5	Home Rule	745	732	Muhlenberg
255	Stamping Ground	6	6	Home Rule	643	730	Scott
256	Fleming-Neon	5	5	Home Rule	770	728	Letcher
257	Loretto	6	6	Home Rule	713	722	Marion
258	Woodland Hills	6	6	Home Rule	696	717	Jefferson
259	Seneca Gardens	6	6	Home Rule	696	712	Jefferson
260	Lynch	5	5	Home Rule	747	709	Harlan
261	Corydon	5	5	Home Rule	720	707	Henderson
262	Science Hill	6	6	Home Rule	693	696	Pulaski
263	Bardwell	5	5	Home Rule	723	694	Carlisle
264	Wickliffe	5	5	Home Rule	688	685	Ballard
265	Inez	6	6	Home Rule	717	684	Martin
266	Barlow	6	6	Home Rule	675	672	Ballard
267	Spring Valley	6	6	Home Rule	654	671	Jefferson
268	Parkway Village	6	6	Home Rule	650	665	Jefferson
269	Upton	6	6	Home Rule	683	665	Hardin/Larue
270	Brownsboro Farm	6	6	Home Rule	648	664	Jefferson
271	Strathmoor Village	6	6	Home Rule	648	663	Jefferson
272	Rolling Fields	6	6	Home Rule	646	662	Jefferson
273	Kuttawa	5	4	Home Rule	649	661	Lyon
274	Loyall	5	5	Home Rule	1,461	654	Harlan
275	Westwood	6	6	Home Rule	634	651	Jefferson
276	North Middletown	5	5	Home Rule	643	650	Bourbon
277	Pippa Passes	6	6	Home Rule	533	643	Knott
278	Wingo	6	6	Home Rule	632	640	Graves
279	Brooksville	5	5	Home Rule	642	638	Bracken
280	Sandy Hook	5	5	Home Rule	675	630	Elliott
281	Caneyville	6	6	Home Rule	608	620	Grayson
282	Kevil	6	6	Home Rule	376	620	Ballard
283	Bedford	6	6	Home Rule	599	608	Trimble
284	Murray Hill	6	6	Home Rule	582	605	Jefferson
285	Martin	4	4	Home Rule	634	602	Floyd
286	Hardin	5	5	Home Rule	615	599	Marshall
287	Ravenna	5	5	Home Rule	605	590	Estill
288	Butler	5	5	Home Rule	612	588	Pendleton
289	Wellington	6	6	Home Rule	565	579	Jefferson
290	Milton	6	6	Home Rule	574	572	Trimble
291	Park City	5	5	Home Rule	537	555	Barren
292	Hollyvilla	6	6	Home Rule	537	551	Jefferson
293	Wheelwright	6	6	Home Rule	780	551	Floyd
294	Glenview	6	6	Home Rule	531	544	Jefferson
295	Whitesville	6	6	Home Rule	552	538	Daviess
296	Frenchburg	6	6	Home Rule	486	531	Menifee
297	Fordsville	6	6	Home Rule	524	530	Ohio
298	Robards	6	6	Home Rule	515	513	Henderson
299	Drakesboro	5	5	Home Rule	515	509	Muhlenberg
300	Bancroft	6	6	Home Rule	494	508	Jefferson
301	Houston Acres	6	6	Home Rule	507	503	Jefferson

	A	B	C	D	E	F	G
1	City Name	Class as of January 1, 2014	Class as of August 1, 2014	Class as of January 1, 2015	2010 Pop. Census	2015 Pop. Est.	County
302	Plum Springs	6	6	Home Rule	453	490	Warren
303	Sonora	6	6	Home Rule	513	487	Hardin
304	Crestview	6	6	Home Rule	475	486	Campbell
305	Fox Chase	6	6	Home Rule	447	476	Bullitt
306	Benham	5	5	Home Rule	500	470	Harlan
307	Melbourne	6	6	Home Rule	401	467	Campbell
308	Sacramento	6	6	Home Rule	468	461	McLean
309	Riverwood	6	6	Home Rule	446	459	Jefferson
310	Island	6	6	Home Rule	458	458	McLean
311	Forest Hills	6	6	Home Rule	444	457	Jefferson
312	Norbourne Estates	6	6	Home Rule	441	454	Jefferson
313	Briarwood	6	6	Home Rule	435	446	Jefferson
314	Centertown	6	6	Home Rule	423	443	Ohio
315	Moorland	6	6	Home Rule	431	443	Jefferson
316	Campton	6	6	Home Rule	441	431	Wolfe
317	River Bluff	6	6	Home Rule	403	426	Oldham
318	Richlawn	6	6	Home Rule	405	416	Jefferson
319	Wayland	6	4	Home Rule	426	409	Floyd
320	Hazel	6	6	Home Rule	410	406	Calloway
321	Hustonville	5	5	Home Rule	405	399	Lincoln
322	Fredonia	5	5	Home Rule	401	393	Caldwell
323	McHenry	6	6	Home Rule	388	393	Ohio
324	Kingsley	6	6	Home Rule	381	392	Jefferson
325	Trenton	6	6	Home Rule	384	386	Todd
326	Hunters Hollow	6	6	Home Rule	386	381	Bullitt
327	Norwood	6	6	Home Rule	370	381	Jefferson
328	Woodburn	6	6	Home Rule	355	377	Warren
329	Grand Rivers	5	5	Home Rule	382	374	Livingston
330	Meadowview Estates	6	6	Home Rule	363	373	Jefferson
331	Poplar Hills	6	6	Home Rule	362	372	Jefferson
332	Gamaliel	6	6	Home Rule	376	366	Monroe
333	Old Brownsboro Place	6	6	Home Rule	353	365	Jefferson
334	Glencoe	6	6	Home Rule	360	359	Gallatin
335	Hyden	6	6	Home Rule	365	351	Leslie
336	Mount Olivet	5	5	Home Rule	299	346	Robertson
337	Strathmoor Manor	6	6	Home Rule	337	346	Jefferson
338	Sharpsburg	6	6	Home Rule	323	343	Bath
339	Bellewood	6	6	Home Rule	321	332	Jefferson
340	Sadieville	5	5	Home Rule	303	332	Scott
341	Glenview Hills	6	6	Home Rule	319	330	Jefferson
342	Brownsboro Village	6	6	Home Rule	319	328	Jefferson
343	Eubank	6	6	Home Rule	319	324	Lincoln/Pulaski
344	Salt Lick	6	6	Home Rule	303	321	Bath
345	Ghent	6	6	Home Rule	323	320	Carroll
346	Vicco	6	6	Home Rule	334	320	Knott/Perry
347	Druid Hills	6	6	Home Rule	308	318	Jefferson
348	Creekside	6	6	Home Rule	305	316	Jefferson
349	Waverly	6	6	Home Rule	308	312	Union
350	Arlington	6	6	Home Rule	324	310	Carlisle
351	Goose Creek	6	6	Home Rule	294	305	Jefferson

	A	B	C	D	E	F	G
1	City Name	Class as of January 1, 2014	Class as of August 1, 2014	Class as of January 1, 2015	2010 Pop. Census	2015 Pop. Est.	County
352	Spring Mill	6	6	Home Rule	287	299	Jefferson
353	Bradfordsville	6	6	Home Rule	294	298	Marion
354	Smithland	6	6	Home Rule	301	295	Livingston
355	Willisburg	6	6	Home Rule	282	287	Washington
356	Water Valley	6	6	Home Rule	279	282	Graves
357	Broeck Pointe	6	6	Home Rule	272	281	Jefferson
358	Saint Charles	6	6	Home Rule	277	271	Hopkins
359	Wildwood	6	6	Home Rule	261	271	Jefferson
360	Rockport	6	6	Home Rule	266	269	Ohio
361	Ewing	6	6	Home Rule	264	266	Fleming
362	Sparta	6	6	Home Rule	231	266	Gallatin/Owen
363	Berry	6	6	Home Rule	264	263	Harrison
364	Bonnieville	6	6	Home Rule	255	259	Hart
365	Warfield	6	6	Home Rule	269	255	Martin
366	Dover	6	6	Home Rule	252	245	Mason
367	Sanders	6	6	Home Rule	238	236	Carroll
368	Lakeview Heights	6	6	Home Rule	185	235	Rowan
369	Oakland	6	6	Home Rule	225	233	Warren
370	Corinth	6	6	Home Rule	232	232	Grant/Scott
371	Manor Creek	6	6	Home Rule	140	232	Jefferson
372	Woodlawn	6	6	Home Rule	229	232	Campbell
373	Nebo	6	6	Home Rule	236	231	Hopkins
374	Crossgate	6	6	Home Rule	225	230	Jefferson
375	Livingston	6	6	Home Rule	226	225	Rockcastle
376	Mackville	6	6	Home Rule	222	225	Washington
377	Fountain Run	6	6	Home Rule	217	211	Monroe
378	Mentor	6	6	Home Rule	193	211	Campbell
379	Slaughters	6	6	Home Rule	216	209	Webster
380	Bremen	6	6	Home Rule	197	195	Muhlenberg
381	Glenview Manor	6	6	Home Rule	191	193	Jefferson
382	Allen	6	6	Home Rule	193	186	Floyd
383	Worthville	6	6	Home Rule	185	184	Carroll
384	South Carrollton	6	6	Home Rule	184	182	Muhlenberg
385	Thornhill	6	6	Home Rule	178	182	Jefferson
386	Maryhill Estates	6	6	Home Rule	179	181	Jefferson
387	Cambridge	6	6	Home Rule	175	179	Jefferson
388	Lafayette	6	6	Home Rule	165	171	Christian
389	Mockingbird Valley	6	6	Home Rule	167	169	Jefferson
390	Sycamore	6	6	Home Rule	160	164	Jefferson
391	Columbus	5	6	Home Rule	170	160	Hickman
392	Prestonville	6	6	Home Rule	161	160	Carroll
393	Buckhorn	6	6	Home Rule	162	159	Perry
394	Blackey	6	6	Home Rule	120	158	Letcher
395	Rochester	6	6	Home Rule	152	156	Butler
396	Wheatcroft	6	6	Home Rule	160	155	Webster
397	Germantown	6	6	Home Rule	154	150	Bracken/Mason
398	Lincolnshire	6	6	Home Rule	148	150	Jefferson
399	Ekron	6	6	Home Rule	135	146	Meade
400	Fairview	6	6	Home Rule	143	146	Kenton
401	Hills and Dales	6	6	Home Rule	142	144	Jefferson

	A	B	C	D	E	F	G
1	City Name	Class as of January 1, 2014	Class as of August 1, 2014	Class as of January 1, 2015	2010 Pop. Census	2015 Pop. Est.	County
402	Meadowbrook Farm	6	6	Home Rule	136	138	Jefferson
403	Monterey	6	6	Home Rule	138	137	Owen
404	Raywick	6	6	Home Rule	134	136	Marion
405	Hickory Hill	6	6	Home Rule	114	115	Jefferson
406	Fairfield	6	6	Home Rule	113	114	Nelson
407	Kenton Vale	6	6	Home Rule	110	112	Kenton
408	Smithfield	6	6	Home Rule	106	107	Henry
409	Ten Broeck	6	6	Home Rule	103	104	Jefferson
410	Sardis	6	6	Home Rule	103	100	Mason/Robertson
411	Woodbury	6	6	Home Rule	90	92	Butler
412	California	6	6	Home Rule	90	86	Campbell
413	Gratz	6	6	Home Rule	78	77	Owen
414	Booneville	6	4	Home Rule	81	76	Owsley
415	Carrsville	6	6	Home Rule	50	49	Livingston
416	Blaine	6	6	Home Rule	47	47	Lawrence
417	Concord	6	6	Home Rule	35	35	Lewis
418	South Park View	6	6	Home Rule	7	7	Jefferson

AOC-105 Rev. 1-07 Page 1 of 1 Commonwealth of Kentucky Court of Justice www.courts.ky.gov CR 4.02; CR Official Form 1	 CIVIL SUMMONS	Case No. <u>19-CJ-940</u> Court <input checked="" type="checkbox"/> Circuit <input type="checkbox"/> District County <u>Franklin</u>
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PLAINTIFF

Hardin County Fiscal Court, On Behalf of Hardin County, et al.,

VS.

DEFENDANT

Purdue Pharma, L.P., et. al.

Service of Process Agent for Defendant:West-Ward Pharmaceuticals Corp.246 Industrial Way WestEatontown, NJ 07724**THE COMMONWEALTH OF KENTUCKY
TO THE ABOVE-NAMED DEFENDANT(S):**

You are hereby notified a **legal action has been filed against you** in this Court demanding relief as shown on the document delivered to you with this Summons. **Unless a written defense is made by you or by an attorney on your behalf within 20 days** following the day this paper is delivered to you, judgment by default may be taken against you for the relief demanded in the attached Complaint.

The name(s) and address(es) of the party or parties demanding relief against you are shown on the document delivered to you with this Summons.

Date: 9/13, 2 019 Amy E Idman Clerk
By: SM D.C.

Proof of Service

This Summons was served by delivering a true copy and the Complaint (or other initiating document) to:

West-Ward Pharmaceuticals Corpthis 20 day of September, 2 019.Served by: Savannah Tate

Title

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September 23, 2019 at 2:05 pm
Delivered
EATONTOWN, NJ 07724

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Proof of Delivery	▾
Tracking History	▴

September 23, 2019, 2:05 pm
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September 23, 2019, 8:18 am
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September 22, 2019, 9:11 am
Arrived at Hub
EATONTOWN, NJ 07724

September 22, 2019, 5:24 am
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TRENTON NJ DISTRIBUTION CENTER

September 22, 2019, 4:25 am
Arrived at USPS Regional Facility

Feedback

Case: 3:17-md-02804-DAP Doc #: 31621 Filed: 10/28/19 Page: 35 of 49 Page ID #: 1014

TRENTON NJ DISTRIBUTION CENTER

September 22, 2019, 3:10 am
Departed USPS Regional Facility
NEWARK NJ DISTRIBUTION CENTER

September 21, 2019, 9:32 pm
Arrived at USPS Regional Destination Facility
NEWARK NJ DISTRIBUTION CENTER

September 21, 2019, 5:22 am
Departed USPS Regional Facility
LOUISVILLE KY DISTRIBUTION CENTER

September 20, 2019, 11:32 pm
Arrived at USPS Regional Origin Facility
LOUISVILLE KY DISTRIBUTION CENTER

September 20, 2019, 10:17 pm
Accepted at USPS Origin Facility
LOUISVILLE, KY 40223

September 20, 2019, 1:35 pm
Shipment Received, Package Acceptance Pending
LOUISVILLE, KY 40243

September 20, 2019
Pre-Shipment Info Sent to USPS, USPS Awaiting Item

Feedback

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FAQs

September 24, 2019

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9410 8036 9930 0113 4843 00.

Item Details



Status:	Delivered
Status Date / Time:	September 23, 2019, 2:05 pm
Location:	EATONTOWN, NJ 07724
Postal Product:	Priority Mail®
Extra Services:	Signature Confirmation™ Up to \$50 insurance included
Recipient Name:	WEST WARD PHARMACEUTICALS CORP
Actual Recipient Name:	A JONES

Note: Actual Recipient Name may vary if the intended recipient is not available at the time of delivery.

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
FRANKFORT DIVISION

CITY OF HENDERSON, KENTUCKY,
ON BEHALF OF THEMSELVES AND
ALL OTHER SIMILARLY SITUATED
HOME RULE CITIES,

PLAINTIFFS,

v.

PURDUE PHARMA L.P., ET AL.,

DEFENDANTS.

No. 3:19-cv-00067-GFVT

DECLARATION

I, Savannah N. Drake, make the following Declaration pursuant to 28 U.S.C. §1746.

1. On September 20, 2019, I prepared and remitted service of the Complaint in this action to Defendant West-Ward Pharmaceuticals Corp. at its corporate address and U.S. headquarters.

2. The Complaint was delivered and signed for by agents for Defendant West-Ward Pharmaceuticals Corp. on September 23, 2019 at 2:05 p.m.

3. A true and accurate copy of the summons and proof of service is provided in Exhibit B to the Plaintiffs' Motion to Remand.

Executed this 28th day of October 2019.



Savannah N. Drake

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
FRANKFORT DIVISION**

**CITY OF HENDERSON, KENTUCKY,
ON BEHALF OF THEMSELVES AND
ALL OTHER SIMILARLY SITUATED
HOME RULE CITIES,**

PLAINTIFFS,

v.

PURDUE PHARMA L.P., ET AL.,

DEFENDANTS.

No. 3:19-cv-00067-GFV

ORDER

Plaintiff, on behalf of itself and the Putative Class, (collectively the “Ky Home Rule City Class”), has filed a timely *Motion to Remand* their complaint to Kentucky State Court because *inter alia* this Court does *not* have the requisite subject matter jurisdiction over their claims based on and arising solely from Kentucky law. The Court being otherwise sufficiently advised,

IT IS HEREBY ORDERED; Plaintiffs’ motion is **GRANTED.**

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
AT FRANKFORT**

CITY OF HENDERSON, KENTUCKY, ON
BEHALF OF THEMSELVES AND ALL
OTHER SIMILARLY SITUATED HOME
RULE CITIES,

Plaintiff,

v.

PURDUE PHARMA L.P., et al.,

Defendants.

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Civil Action No. 3:19-CV-00067-

GFVT

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**MCKESSON CORPORATION'S BRIEF IN OPPOSITION TO
PLAINTIFF'S MOTION TO REMAND**

TABLE OF CONTENTS

INTRODUCTION	1
BACKGROUND	2
A. Plaintiff’s Action.....	2
B. The Multidistrict Litigation.....	4
ARGUMENT	5
I. The Complaint Satisfies the CAFA Jurisdictional Requirements.....	5
A. The class is sufficiently numerous.....	6
B. The local controversy exception does not apply.	7
II. McKesson’s Supplemental Notice of Removal Satisfied the Procedural Requirements....	9
A. McKesson obtained consent from all defendants that were properly served.....	9
B. The State Government Defendants should be realigned for purposes of removal.	10
III. This Case Is Subject to Federal Question Jurisdiction.....	12
A. The Complaint “necessarily raises” federal issues.	13
B. The parties “actually dispute” the federal issue.....	16
C. The federal issues are “substantial.”	17
D. Federal jurisdiction will not disrupt the Congressionally approved balance of federal-state judicial responsibilities.....	20
IV. The Remand Decisions Plaintiff Cites Are Distinguishable and the MDL Court Has Not Rejected McKesson’s Asserted Ground for Removal.	21
V. The Court Should Defer Consideration of Plaintiff’s Remand Motion.....	23
CONCLUSION.....	23

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>In Re Admin. Subpoena Walgreen Co. v. DEA</i> , 913 F. Supp. 2d 243 (E.D. Va. 2012)	20
<i>Bd. of Comm’rs of Se. La. Flood Prot. Auth.-E. v. Tenn. Gas Pipeline Co.</i> , 850 F.3d 714 (5th Cir. 2017)	17, 20
<i>Bracken Cty. v. AmerisourceBergen Drug Corp.</i> , No. 2:18-cv-41 (E.D. Ky.)	4
<i>Broder v. Cablevision Sys. Corp.</i> , 418 F.3d 187 (2d Cir. 2005).....	11, 12, 18
<i>Byrd v. Wine</i> , 2017 WL 67993 (M.D. Tenn. Jan. 6, 2017).....	10
<i>Cardinal Health, Inc. v. Holder</i> , 846 F. Supp. 2d 203 (D.D.C. 2012)	20
<i>Caterpillar, Inc. v. Williams</i> , 482 U.S. 386 (1987).....	14, 15
<i>City of Chicago v. Int’l Coll. of Surgeons</i> , 522 U.S. 156 (1997).....	12
<i>Cleveland Hous. Renewal Project v. Deutsche Bank Tr. Co.</i> , 621 F.3d 554 (6th Cir. 2010)	11
<i>Davenport v. Lockwood, Andrews & Newnam, Inc.</i> , 854 F.3d 905 (6th Cir. 2017)	8
<i>Dickens v. Oxy Vinyls, LP</i> , 631 F. Supp. 2d 859 (W.D. Ky. 2009).....	15
<i>Exxon Mobil Corp. v. Allapattah Servs., Inc.</i> , 545 U.S. 546 (2005).....	12
<i>Foremost Ins. Co. v. Whitaker</i> , 892 S.W.2d 607 (Ky. App. 1995)	9
<i>Freeman v. Blue Ridge Paper Prods., Inc.</i> , 551 F.3d 405 (6th Cir. 2008)	6, 7

<i>Gilmore v. Weatherford</i> , 694 F.3d 1160 (10th Cir. 2012)	15
<i>Grable & Sons Metal Products, Inc. v. Darue Eng’g & Mfg.</i> , 545 U.S. 308 (2005).....	2, 12, 13, 17
<i>Gunn v. Minton</i> , 568 U.S. 251 (2013).....	<i>passim</i>
<i>Harper v. AutoAlliance Int’l, Inc.</i> , 392 F.3d 195 (6th Cir. 2004)	10
<i>New York ex rel. Jacobson v. Wells Fargo Nat’l Bank, NA</i> , 824 F.3d 308 (2d Cir. 2016).....	12, 13, 18, 19
<i>Johnson v. BLC Lexington SNF, LLC</i> , 2019 WL 2216441 (E.D. Ky. May 22, 2019)	7, 8
<i>Jr. Food Stores, Inc. v. Hartland Constr. Grp., LLC</i> , 2019 WL 5430355 (W.D. Ky. Oct. 23, 2019)	10
<i>Lontz v. Tharp</i> , 413 F.3d 435 (4th Cir. 2005)	14
<i>Mason v. Lockwood, Andrews & Newnam, P.C.</i> , 842 F.3d 383 (6th Cir. 2016)	7
<i>Masters Pharm., Inc. v. DEA</i> , 861 F.3d 206 (D.C. Cir. 2017)	3, 13, 14
<i>Melrose Park v. McKesson Corp.</i> , No. 1:18-cv-05288 (N.D. Ill. Aug. 10, 2018), ECF No. 26	22
<i>Merrell Dow Pharms. v. Thompson</i> , 478 U.S. 804 (1986).....	13
<i>NASDAQ OMX Grp., Inc. v. UBS Sec., LLC</i> , 770 F.3d 1010 (2d Cir. 2014).....	<i>passim</i>
<i>Ohio ex rel. Skaggs v. Brunner</i> , 588 F. Supp. 2d 819 (S.D. Ohio 2008), <i>vacated on other grounds</i> , 549 F.3d 468 (6th Cir. 2008)	10
<i>Osage Cty. v. Purdue Pharma LP</i> , No. 4:18-cv-00461 (N.D. Okla. Nov. 14, 2018), ECF No. 87	22
<i>In re Nat’l Prescription Opiate Litig.</i> , 2019 WL 180246 (N.D. Ohio Jan. 14, 2019).....	21

<i>In re Nat’l Prescription Opiate Litig.</i> , 290 F. Supp. 3d 1375, 1378-79 (J.P.M.L. 2017)	4
<i>PDK Labs. Inc. v. DEA</i> , 362 F.3d 786 (D.C. Cir. 2004)	20
<i>PNC Bank, N.A. v. PPL Elec. Utils. Corp.</i> , 189 F. App’x 101 (3d Cir. 2006)	12, 13
<i>Portland v. Purdue Pharma LP</i> , No. 2:18-cv-00282 (D. Me. Nov. 28, 2018), ECF No. 96	22
<i>R.I. Fishermen’s All. v. R.I. Dep’t of Env’tl. Mgmt.</i> , 585 F.3d 42 (1st Cir. 2009)	15
<i>Ranck v. Mt. Hood Cable Regulatory Comm’n</i> , 2017 WL 1752954 (D. Or. May 2, 2017)	13
<i>Seminole Cty. v. Purdue Pharma LP</i> , No. 6:18-cv-00372 (E.D. Okla. Apr. 3, 2019), ECF No. 51	22
<i>In re Southwood Pharm., Inc.</i> , 72 Fed. Reg. 36,487, 2007 WL 1886484 (DEA July 3, 2007)	3
<i>United States v. Sigma Int’l, Inc.</i> , 300 F.3d 1278 (11th Cir. 2002)	21
<i>V.I. Hous. Auth. v. Coastal Gen. Constr. Servs. Corp.</i> , 27 F.3d 911 (3d Cir. 1994)	13
Statutes	
21 U.S.C. § 882(a)	20
21 U.S.C. § 903	20
28 U.S.C. § 1331	2, 11, 13
28 U.S.C. § 1332(d)	5, 6, 7
28 U.S.C. § 1441(a)	11
29 U.S.C. § 1446(b)	10
Ky. Rev. Stat. Ann. § 454.210	9
Other Authorities	
21 C.F.R. § 1301.74(b)	3, 13

Bertelsman & Philipps, <i>Kentucky Practice</i> , Civil Rule 4.04, Vol. 6, p. 34 (4th ed. 1984)	9
H.R. Rep. No. 91-1444 (1970), <i>reprinted in</i> 1970 U.S.C.C.A.N. 4566	18

INTRODUCTION

This case belongs in federal court for two reasons: (1) Plaintiff’s class Complaint meets the requirements for removal under the Class Action Fairness Act of 2005 (“CAFA”); and (2) the Court has federal question jurisdiction over Plaintiff’s claims, which depend on alleged breaches of federal duties. Plaintiff’s remand motion eschews substantive arguments about federal jurisdiction in favor of demonstrably incorrect arguments about federal procedure. Plaintiff’s failure to address the substance of McKesson’s removal compels denial of its remand motion.

However, this Court need not even reach the merits of Plaintiff’s remand motion. The Court instead should defer consideration of Plaintiff’s remand motion and allow the jurisdictional issues presented to be decided on a national basis alongside similar claims brought by other plaintiffs across the country, as part of the national opioid litigation that has been consolidated for pre-trial purposes by the Judicial Panel on Multidistrict Litigation (“JPML”) in the Northern District of Ohio (the “MDL”).

If this Court decides to reach the merits of Plaintiff’s remand motion, the Court should deny that motion. Federal jurisdiction is appropriate under CAFA because Plaintiff purports to represent a “minimally diverse” class seeking an amount in controversy above the CAFA threshold. Plaintiff challenges CAFA jurisdiction, arguing that the purported class falls below the CAFA numerosity threshold of 100 plaintiffs. This creative math required artful pleading of a type that the Sixth Circuit has rejected. Specifically, on the same day that Plaintiff filed its Complaint purportedly representing 90 *cities*, Plaintiff’s attorneys filed a substantively identical complaint on behalf of a putative class of 65 Kentucky *counties*. These parallel cases seek identical relief from the identical defendants based on identical factual allegations. Plaintiff does not explain how the city and county cases differ, apart from the fact that a county is different than a city. In these circumstances, Sixth Circuit precedent requires that the “two” classes be

aggregated for purposes of measuring CAFA numerosity, and the aggregate class indisputably exceeds 100.

Plaintiff's reliance on alleged duties arising under federal law creates an independent basis for removal: federal question jurisdiction under 28 U.S.C. § 1331, and under the Supreme Court's four-part test set forth in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005), and *Gunn v. Minton*, 568 U.S. 251 (2013). Removal is proper because Plaintiff asserts claims that McKesson and other distributors of prescription opioids (collectively, "Distributors") breached legal duties arising under the federal Controlled Substances Act, 21 U.S.C. § 801, *et seq.* (the "CSA").

Plaintiff's main argument on remand—that McKesson was required, but failed, to secure the assent of unserved defendant West-Ward Pharmaceuticals Corp. and adverse State Government "Defendants"—should be rejected. Consent for removal is not required from co-defendants that—like West-Ward—were not properly served; nor is consent required from State Government "Defendants" who in reality are aligned *with Plaintiff* and *against McKesson* with respect to the primary disputes in this action.

For these reasons, the Court should deny Plaintiff's motion to remand.

BACKGROUND¹

A. Plaintiff's Action

Plaintiff filed this lawsuit in Kentucky state court on September 13, 2019. DKY Dkt. No. 1, Ex. A. On October 4, 2019, Plaintiff filed a First Amended Class Action Complaint (the "Complaint"). DKY Dkt. No. 81 ¶ 1. The Complaint identifies four groups of defendants: (i) pharmaceutical manufacturers (and certain directors, former directors, and executives

¹ "JPML Dkt." refers to the JPML's docket in *In re National Prescription Opiate Litigation*, MDL No. 2804 (J.P.M.L.), and "DKY Dkt." refers to the Court's docket in this action.

thereof), which make and promote opioid medications; (ii) Distributors, which are pharmaceutical wholesale distributors; (iii) retail pharmacies; and (iv) Kentucky officials and agencies (the “State Government Defendants”). *Id.* ¶¶ 2-6. The Complaint asserts causes of action against defendants other than the State Government Defendants for: public nuisance; negligence; negligence *per se* (two counts); negligent misrepresentation; civil conspiracy (two counts); consumer protection; fraud by omission; unjust enrichment; and punitive damages. *Id.* ¶ 7.

Plaintiff’s central theory of liability against Distributors is that Distributors allegedly violated duties aimed at preventing “diversion” of controlled substances, including purported duties to “report” and “refuse” shipments of suspicious orders. *See, e.g.*, Compl. ¶ 450 (Distributors “breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates”). According to the Complaint, Kentucky law “adopted and incorporated” requirements established by and under the federal CSA. *See* Compl. ¶¶ 429, 430, 432. Indeed, the CSA is the sole source of Distributors’ alleged duties—Plaintiff identifies *no* Kentucky law creating duties other than those already contained in the federal CSA and its implementing federal regulations. The alleged reporting duty that Plaintiff relies on is set forth in the CSA’s implementing regulations. *See* 21 C.F.R. § 1301.74(b) (duty to monitor and report suspicious orders of controlled substances). The alleged shipment-refusal duty likewise arises, if at all, out of the Drug Enforcement Administration’s (“DEA”) interpretation of the CSA, pursuant to which Distributors must “decline to ship” suspicious orders for controlled substances. *See Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 212-13 (D.C. Cir. 2017) (citing *In re Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,500-501, 2007 WL 1886484 (DEA July 3, 2007), as the source of DEA’s “Shipping Requirement”). The claims in the Complaint thus

depend on allegations that Distributors violated federal duties arising under the CSA and related DEA regulations.

B. The Multidistrict Litigation

Not only does Plaintiff base its claims on federal law, its claims are similar to those being asserted in federal court by hundreds of other municipalities and other plaintiffs against opioid manufacturers, distributors, pharmacies, and doctors. To consolidate these cases for coordinated pre-trial proceedings, the JPML formed an MDL in the Northern District of Ohio. *See In re Nat'l Prescription Opiate Litig.*, 290 F. Supp. 3d 1375, 1378-79 (J.P.M.L. 2017). In total, more than 2,300 actions are now pending in the MDL, including numerous actions originally filed in or removed to federal courts in Kentucky.² As new cases are filed across the country each week, the JPML continues—and will continue—to transfer more actions to the MDL.

Upon removal, a notice was filed with the JPML tagging this case for potential transfer to the MDL. *See* JPML Dkt. No. 5732. Based on that notice, the JPML issued an order conditionally transferring the action to the MDL on the ground that it appears to “involve

² *See, e.g., Cty. of Floyd v. Purdue Pharma L.P.*, No. 7:17-cv-00186 (E.D. Ky.); *Cty. of Pike v. Teva Pharmaceuticals USA, Inc.*, No. 7:17-cv-00193 (E.D. Ky.); *Cty. of Knott v. Purdue Pharma L.P.*, No. 7:18-cv-00006 (E.D. Ky.); *Saint Elizabeth Med. Ctr. Inc., v. AmerisourceBergen Drug Corp.*, No. 2:18-cv-146 (E.D. Ky.); *Kentucky League of Cities Insurance Services v. Purdue Pharma L.P.*, No. 5:18-cv-00471 (E.D. Ky.); *City of Covington v. Purdue Pharma L.P.*, No. 2:18-cv-131 (E.D. Ky.); *Elliot Cty. v. AmerisourceBergen Drug Corp.*, No. 0:18-cv-36 (E.D. Ky.); *Carter Cty. v. AmerisourceBergen Drug Corp.*, No. 0:18-cv-35 (E.D. Ky.); *Bracken Cty. v. AmerisourceBergen Drug Corp.*, No. 2:18-cv-41 (E.D. Ky.); *Wayne Cty. v. AmerisourceBergen Drug Corp.*, No. 6:18-cv-89 (E.D. Ky.); *Martin Cty. v. AmerisourceBergen Drug Corp.*, No. 7:18-cv-36 (E.D. Ky.); *Cty. of Woodford v. AmerisourceBergen Drug Corp.*, No. 5:17-cv-00475 (E.D. Ky.); *Cty. of Scott v. AmerisourceBergen Drug Corp.*, No. 5:17-cv-00474 (E.D. Ky.); *Cty. of Rowan v. AmerisourceBergen Drug Corp.*, No. 0:17-cv-00130 (E.D. Ky.); *Cty. of Clark v. AmerisourceBergen Drug Corp.*, No. 5:17-cv-00473 (E.D. Ky.); *Cty. of Jessamine v. AmerisourceBergen Drug Corp.*, No. 5:17-cv-438 (E.D. Ky.); *Lexington-Fayette Urban Cty. Gov't v. AmerisourceBergen Drug Corp.*, No. 5:17-cv-442 (E.D. Ky.); *Whitley Cty. v. AmerisourceBergen Drug Corp.*, No. 6:17-cv-250 (E.D. Ky.); *Shelby Cty. v. AmerisourceBergen Drug Corp.*, No. 3:17-cv-72 (E.D. Ky.).

questions of fact that are common to the actions previously transferred to the Northern District of Ohio and assigned to Judge Polster.” JPML Dkt. No. 5740 (attached as **Exhibit 1**).

Plaintiff thereafter filed an opposition to transfer with the JPML. JPML Dkt. No. 5834. As a result, the JPML automatically stayed its conditional order and issued a briefing schedule. JPML Dkt. No. 5898. Briefing on transfer will conclude on November 22, 2019, and McKesson anticipates that the JPML will make a final transfer decision shortly after its hearing on January 30, 2020, or the next available hearing thereafter. *See* U.S. Judicial Panel on Multidistrict Litigation, Hearing Information, <http://www.jpml.uscourts.gov/hearing-information> (last accessed Nov. 14, 2019).

Contemporaneously with this opposition, McKesson has moved to stay this action in its entirety pending the JPML’s final transfer decision.

ARGUMENT

Plaintiff’s transparent attempts to artfully plead around CAFA jurisdiction must be rejected. Additionally, given Plaintiff’s reliance on duties arising under federal law, federal question jurisdiction is proper. Although Plaintiff purports to assert state law causes of action, its claims are predicated on alleged violations of the CSA. Because those claims necessarily raise substantial federal issues that should be resolved in federal court, Plaintiff’s motion to remand should be denied.

I. THE COMPLAINT SATISFIES THE CAFA JURISDICTIONAL REQUIREMENTS.

Federal courts have jurisdiction under CAFA where: (1) the amount in controversy exceeds \$5 million; (2) minimal diversity exists; and (3) the total number of class members in all proposed classes is 100 or more. 28 U.S.C. § 1332(d). Plaintiff challenges only the third requirement, arguing that there are too few class members. *See* Remand Mot. at 2-6. Plaintiff is

wrong, because the putative class of Kentucky counties and cities exceeds 100.

Plaintiff may not escape CAFA by invoking the so-called “local controversy” exception to CAFA. While Plaintiff identifies two purportedly “local controversy” defendants, they are not defendants “from whom significant relief is sought” and “whose alleged conduct forms a significant basis for the claims asserted,” as required by CAFA. *See* 28 U.S.C. § 1332(d)(4)(A)(i).

A. The class is sufficiently numerous.

Plaintiff’s putative class contains over 100 members. On the same day that Plaintiff’s attorneys filed its Complaint, they also filed a nearly identical amended complaint on behalf of the County of Hardin and a putative class of Kentucky counties. *See Hardin County Fiscal Court, et al. v. Purdue Pharma L.P.*, No. 3:19-cv-00068 (E.D. Ky.). Apart from the parties, the two complaints are virtually identical. *See Exhibit 2*. The complaints seek identical relief against identical defendants based on identical factual allegations. Plaintiffs may not artificially split their suits in this manner to avoid CAFA’s numerosity requirement. *Freeman v. Blue Ridge Paper Prods., Inc.*, 551 F.3d 405, 407 (6th Cir. 2008) (“CAFA was clearly designed to prevent plaintiffs from artificially structuring their suits to avoid federal jurisdiction.”)

Plaintiff seeks to distinguish *Freeman* on the ground that the cities expressly included in this Complaint’s plaintiff class are “not identical” to the cities expressly included in the amended *Hardin* plaintiff class. Remand Mot. at 6. This argument is sophistry. The *reason* the expressly named plaintiff classes are not identical is *because* plaintiffs’ counsel engaged in the type of “artificial[] structuring” forbidden by *Freeman*. *See* 551 F.3d at 408 (CAFA does not “permit the splintering of lawsuits solely to avoid federal jurisdiction in the fashion done in this case”). The two identical complaints could—and *should*—have been filed as a single case requesting

certification of a single class, multiple subclasses, or two separate classes.³

The only plausible reason that Plaintiff elected to structure its suit in this manner was to avoid CAFA jurisdiction; it offers no other justification. *Freeman* is clear that in such circumstances, where “Plaintiffs put forth no colorable reason for breaking up the lawsuits in this fashion, other than to avoid federal jurisdiction,” the court should aggregate the cases for determining CAFA jurisdiction. 551 F.3d at 407. Once aggregated, as Plaintiff admits in the Complaint and the corresponding amended complaint in the *Hardin* case, the plaintiff class exceeds 100. *See* Compl. ¶ 660 (“The Plaintiff Class exceeds sixty (60) Home Rule cities”); *Hardin County Fiscal Court, et al. v. Purdue Pharma L.P.*, No. 3:19-cv-00068 (E.D. Ky. Oct. 4, 2019), ECF No. 6 ¶ 664 (“The Plaintiff Class exceeds sixty (60) Counties”).

Plaintiff’s clever pleading does not stop there, however. Plaintiff also defined the Home Rule City Class as including only those cities “with populations in excess of 4,000.” Remand Mot. at 4. Plaintiff offers no explanation for why a city with a population of 4,000 must be excluded from its proposed class, while a city of 4,001 should be included. Indeed, the only plausible reason for this limitation is to avoid CAFA jurisdiction. There are hundreds of home rule cities in Kentucky, including more than 100 cities with populations in excess of 3,000. *See* Remand Mot. Ex. A (“Kentucky City Classification”). Plaintiff’s unexplained population limitation betrays that the sole goal of the two class definitions is to “avoid federal jurisdiction.” *Freeman*, 551 F.3d at 407.

B. The local controversy exception does not apply.

Plaintiff attempts to invoke the “local controversy” exception to CAFA jurisdiction on

³ Although Plaintiff asserts in passing that it “pleaded their complaint . . . in accordance with Kentucky’s rules of civil procedure,” they identify no rule that prohibits a complaint from pleading two classes, or a class with two subclasses.

the basis that two defendants—“CVS Pharmacy” and “Rite Aid KY”—are Kentucky citizens. But this exception only applies if Plaintiff establishes that the conduct of those two defendants “forms a significant basis for [Plaintiff’s] claims.” 28 U.S.C. § 1332(d)(4)(A)(i); *Mason v. Lockwood, Andrews & Newnam, P.C.*, 842 F.3d 383, 389 (6th Cir. 2016). Plaintiff does not come close to meeting this burden.

To establish that CVS Pharmacy and Rite Aid KY’s conduct “forms a significant basis” for Plaintiff’s claims, Plaintiff would have to have compared “the conduct of the local defendants . . . to the actions of all of the defendants.” *Johnson v. BLC Lexington SNF, LLC*, 2019 WL 2216441, at *5 (E.D. Ky. May 22, 2019) (citing *Mason*, 842 F.3d at 395-96). Plaintiff made no attempt to do that. Instead, it simply asserts, without citation, that the local “pharmacy defendants were substantially involved in the sale and distribution of opioids throughout the Commonwealth.” Remand Mot. at 7.

Nor could Plaintiff make the required showing, even if it had tried. The Complaint barely mentions CVS Pharmacy and Rite Aid KY, identifying them individually in just a few paragraphs. *See* Compl. ¶¶ 218-220 (identifying “CVS Pharmacy”); ¶¶ 227-229 (identifying “Rite Aid KY”). There are no allegations about how many opioids either of these pharmacies actually dispensed, and their conduct is in no way distinguished from or compared to the conduct of other retail pharmacies, none of which are Kentucky citizens.⁴ *See* Compl. ¶¶ 221-226, 230-235 (describing out-of-state retail pharmacy defendants). A comparison of defendants’ conduct would therefore be impossible, because the Complaint “only ma[kes] comments about the conduct of the defendants generally,” without discussing how the specific conduct of the two local pharmacies differs from that of out-of-state pharmacies. *See Johnson*, 2019 WL 2216441,

⁴ Plaintiff voluntarily dismissed a third “local” defendant. *See* DKY Dkt. 90.

at *5.

Plaintiff does not come close to establishing the applicability of the local controversy exception; and to the extent there were “any doubt about the applicability of [that] exception[, it] should be construed in favor of maintaining federal jurisdiction.” *Id.* (citing *Davenport v. Lockwood, Andrews & Newnam, Inc.*, 854 F.3d 905, 909 (6th Cir. 2017)).

II. MCKESSON’S SUPPLEMENTAL NOTICE OF REMOVAL SATISFIED THE PROCEDURAL REQUIREMENTS.

A. McKesson obtained consent from all defendants that were properly served.

Plaintiff’s primary argument in opposition to McKesson’s supplemental notice of removal is that McKesson failed to secure the consent of all defendants, on the basis that Plaintiff served West-Ward Pharmaceuticals Corp. before McKesson filed its supplemental notice of removal. That is incorrect for two reasons: (1) West-Ward was not properly served prior to removal; and (2) West-Ward has now consented, thereby curing any defect.

Plaintiff’s service on West-Ward was ineffective. The Kentucky Rules of Civil Procedure allow for personal service or service by certified mail. Ky. CR 4.01. Plaintiff employed neither of these methods, instead sending the summons and complaint via U.S. Priority Mail with signature confirmation to “West-Ward Pharmaceuticals Corp.” *See* Remand Mot., Ex. B. Even if Plaintiff’s mode of service had been proper, Plaintiff’s service would still have been ineffective, because Plaintiff did not send its Complaint to an appropriate entity. Because West-Ward is an out-of-state corporation, Kentucky’s long-arm statute required Plaintiff to make service on either the Kentucky Secretary of State under, Ky. Rev. Stat. Ann. § 454.210, or on an entity that West-Ward designated to receive service of process, *see* Ky. CR 4.04.

And even if Plaintiff had been permitted to serve its Complaint directly on West-Ward, by priority mail, service still would have been ineffective because it was merely addressed to the

home office of the corporation rather than to “an officer or managing agent thereof, or the chief agent in the county wherein the action is brought, or any other agent authorized by appointment or by law to receive service on its behalf.” Ky. CR 4.04(5). “If the interpretation were permitted that the corporation could be validly served by addressing the certified envelope merely in the corporate name to be delivered at the home office, there is too much risk that the process would not find its way into the hands of a reasonable person.” *Foremost Ins. Co. v. Whitaker*, 892 S.W.2d 607, 610 (Ky. App. 1995) (citing Bertelsman & Philipps, *Kentucky Practice*, Civil Rule 4.04, Vol. 6, p. 34 (4th ed. 1984)) (emphasis removed). Because Plaintiff’s service on West-Ward was ineffective for multiple reasons, West-Ward’s consent to removal was not required. *See* 29 U.S.C. § 1446(b) (consent is required only from those defendants “who have been properly joined and served”).

In any event, West-Ward *has consented* to removal of this action, as indicated by the declaration attached to this Opposition as **Exhibit 3**. Even where a defendant fails explicitly to consent in advance to removal, that defendant’s joinder in a subsequent opposition to remand “communicate[s] [its] consent and desire to be in federal court,” curing any alleged defect. *Jr. Food Stores, Inc. v. Hartland Constr. Grp., LLC*, 2019 WL 5430355, at *1-2 (W.D. Ky. Oct. 23, 2019); *see also Harper v. AutoAlliance Int’l, Inc.*, 392 F.3d 195, 202 (6th Cir. 2004) (finding that a post-removal answer conceding that jurisdiction and venue in federal court was sufficient to cure any purported failure to consent to a notice of removal).

B. The State Government Defendants should be realigned for purposes of removal.

Plaintiff also contends that McKesson was required, but failed, to secure the consent of the State Government Defendants. Remand Mot. at 10. Such consent was not necessary, however, because the State Government Defendants are properly aligned with Plaintiff, not with

the other defendants. *See, e.g., Byrd v. Wine*, 2017 WL 67993, at *7-8 (M.D. Tenn. Jan. 6, 2017) (“Given the fact that [certain defendants’] interests accord with [the plaintiff’s] and conflict with [the removing defendant], the Court will realign them. . . . Given that [those defendants] will be realigned as plaintiffs, their consent to removal is not required.”); *Ohio ex rel. Skaggs v. Brunner*, 588 F. Supp. 2d 819, 826-27 (S.D. Ohio 2008) (“[T]he Court determined . . . that Defendant FBOE’s interests were aligned with the Plaintiffs’ interests and, therefore, GRANTED the Secretary’s Motion to Realign Parties. That ruling made the FBOE a plaintiff in this case. In light of the Court’s ruling on the Motion to Realign, the FBOE’s lack of consent to removal is no longer an issue as the FBOE is now aligned with the plaintiffs in this case.” (internal citation omitted)), *vacated on other grounds*, 549 F.3d 468 (6th Cir. 2008)

The Commonwealth has sued McKesson asserting claims nearly identical to those that Plaintiff brings against McKesson. *See* DKY Dkt. 82 ¶¶ 53-54. The State Government Defendants stand adverse to McKesson and the other defendants in precisely the way Plaintiff does. It would require suspending reality to treat the State Government Defendants as *aligned with* McKesson and the other defendants, and thus to require McKesson to obtain the State Government Defendants’ consent.

Plaintiff ignores these dispositive points—and all of the legal authority cited in McKesson’s supplemental notice—and instead simply notes that its Complaint includes certain claims solely against the State Government Defendants, and that they are adverse parties with respect to those claims. Remand Mot. at 9-10. But superficial “adversity” in the caption is not what matters. Instead, “[p]arties must ‘be aligned in accordance with the primary dispute in the controversy, even where a different, legitimate dispute between the parties supports the original alignment.’” *Cleveland Hous. Renewal Project v. Deutsche Bank Tr. Co.*, 621 F.3d 554, 559

(6th Cir. 2010) (internal citations omitted). The “primary dispute in controversy” in this action consists of Plaintiff’s claims against pharmaceutical manufacturers, distributors, and pharmacies; and Plaintiff and the State Government Defendants are aligned with each other and against those other defendants with respect to those claims.

III. THIS CASE IS SUBJECT TO FEDERAL QUESTION JURISDICTION.

Federal district courts have removal jurisdiction over “any civil action brought in a State court of which the district courts of the United States have original jurisdiction,” 28 U.S.C. § 1441(a), and original jurisdiction over “all civil actions arising under the Constitution, laws, or treaties of the United States,” 28 U.S.C. § 1331. “A single claim over which federal-question jurisdiction exists is sufficient to allow removal.” *Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 194 (2d Cir. 2005); *see Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 563 (2005); *City of Chicago v. Int’l Coll. of Surgeons*, 522 U.S. 156, 164–66 (1997).

Even where state law creates the causes of action asserted in a complaint, one or more of those causes of action may raise a federal question sufficient to warrant removal jurisdiction. Under the Supreme Court’s *Grable* and *Gunn* decisions, “federal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress.” *Gunn*, 568 U.S. at 258; *see also Grable*, 545 U.S. at 315. “Where all four of these requirements are met . . . jurisdiction is proper because there is a serious federal interest in claiming the advantages thought to be inherent in a federal forum, which can be vindicated without disrupting Congress’s intended division of labor between state and federal courts.” *Gunn*, 568 U.S. at 258 (quotation marks omitted).

Courts have found these factors satisfied in cases where state law claims are predicated on violations of federal statutes governing complex, nationwide regulatory schemes for which

uniformity is essential. *See, e.g., PNC Bank, N.A. v. PPL Elec. Utils. Corp.*, 189 F. App'x 101, 104 n.3 (3d Cir. 2006) (state law claim based on violation of Internal Revenue Code “gives rise to federal-question jurisdiction” under *Grable*); *Broder*, 418 F.3d at 196 (state law claims premised on cable provider’s alleged violations of Communication Act’s uniform rate requirement satisfy “*Grable* test for federal-question removal jurisdiction”); *NASDAQ OMX Grp., Inc. v. UBS Sec., LLC*, 770 F.3d 1010, 1031 (2d Cir. 2014) (state law claims premised on violations of Exchange Act “necessarily raise disputed issues of federal law of significant interest to the federal system as a whole”); *New York ex rel. Jacobson v. Wells Fargo Nat’l Bank, NA*, 824 F.3d 308, 315–18 (2d Cir. 2016) (state law claims based on defendant’s alleged violation of Internal Revenue Code satisfy *Grable*); *Ranck v. Mt. Hood Cable Regulatory Comm’n*, 2017 WL 1752954, at *5 (D. Or. May 2, 2017) (state law claims based on violations of Cable Communications Policy Act satisfy *Grable*).

This case satisfies all four elements of *Grable* and *Gunn*.

A. The Complaint “necessarily raises” federal issues.

An action “necessarily raises” a federal question when “the right to relief depends upon the construction or application of federal law.” *PNC Bank*, 189 F. App'x at 104 n.3. Significantly, “an action under 28 U.S.C. § 1331(a) arises . . . if the action requires construction of a federal statute, or at least a distinctive policy of a federal statute requires the application of federal legal principles.” *V.I. Hous. Auth. v. Coastal Gen. Constr. Servs. Corp.*, 27 F.3d 911, 916 (3d Cir. 1994) (emphasis added); *see also Merrell Dow Pharms. v. Thompson*, 478 U.S. 804, 808–09 (1986) (federal question jurisdiction exists if “vindication of a right under state law necessarily turn[s] on some construction of federal law” (citation omitted)). In determining whether state law claims turn on construction or application of federal law, the Court must “begin by considering the duty underlying each claim.” *NASDAQ*, 770 F.3d at 1020. “A state-

law claim ‘necessarily’ raises federal questions where the claim is affirmatively ‘premised’ on a violation of federal law,” *Jacobson*, 824 F.3d at 315, or where the “singular duty” underlying the claim arises under federal law, *NASDAQ*, 770 F.3d at 1021.

Here, Plaintiff’s claims necessarily raise federal issues because they are expressly premised on Distributors’ alleged violations of alleged legal duties that arise out of the CSA and its implementing regulations—i.e., the duties to report and halt suspicious orders for controlled substances. See 21 C.F.R. § 1301.74(b) (setting forth reporting requirement); *Masters Pharm.*, 861 F.3d at 212-13 (discussing shipping requirement).

While Plaintiff denies it, its reliance on federal law is evident on the face of the Complaint. See *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 392 (1987) (federal jurisdiction exists when federal question is presented “on the face of the plaintiff’s properly pleaded complaint”); *Lontz v. Tharp*, 413 F.3d 435, 439 (4th Cir. 2005) (removal “is appropriate if the face of the complaint raises a federal question”).

Throughout the Complaint, Plaintiff cites to federal laws, federal regulations, and DEA guidance, not as mere “factual reference[s],” Remand Mot. at 13, but *to establish the duties*, the alleged breach of which *constitutes Plaintiff’s causes of action*, e.g.:

- “Each of the Wholesale Distributor Defendants was further required to register with the DEA, pursuant to the federal Controlled Substance[s] Act as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Those requirements were adopted and incorporated into Kentucky law.” Compl. ¶ 429.
- “As ‘registrants’ under the CSA, the Opioid Supply Defendants were and remain duty bound to identify and report ‘orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.’” Compl. ¶ 615.
- “The Court of Appeals for the District of Columbia recently confirmed that wholesale drug distributors have duties and legal obligations *beyond reporting*.” Compl. ¶ 459 (emphasis in the original) (citing *Masters Pharm., Inc. v. Drug*

Enf't Admin., 861 F.3d 206 (D.C. Cir. 2017)).

As these and other passages demonstrate, Plaintiff's claims against Distributors rest squarely on its allegations that Distributors breached duties that, according to Plaintiff itself, arise out of the CSA and its implementing regulations. Plaintiff's motion to remand ignores the allegations of its Complaint, brushing aside its reliance on the CSA as "a factual reference to a federal database [*sic*] (the "CSA") and corresponding reporting requirement." Remand Mot. at 11. To the contrary, Plaintiff's invocation of the CSA and other federal sources undergird its entire theory of liability against Distributors.

The fact that Kentucky law expressly incorporates federal CSA duties further bolsters federal jurisdiction. As one court has explained, the "incorporation of federal law into the state statute on which the plaintiffs' cause of action is grounded" necessarily raises an "embedded federal question." *R.I. Fishermen's All. v. R.I. Dep't of Env'tl. Mgmt.*, 585 F.3d 42, 49, 50-51 (1st Cir. 2009); *e.g.*, *Gilmore v. Weatherford*, 694 F.3d 1160, 1173 (10th Cir. 2012) (state law conversion claim necessarily raises federal question where "Oklahoma personal property law includes and incorporates the federal requirement").

Although a plaintiff "may avoid federal jurisdiction by *exclusive* reliance on state law," *Caterpillar*, 482 U.S. at 392 (emphasis added), Plaintiff's claims here have no such exclusive state law basis. Plaintiff's claim for public nuisance (Count A) illustrates the point. To establish that Distributors caused a public nuisance, Plaintiff must show, among other things, that Distributors' conduct was unreasonable or unlawful. *See Dickens v. Oxy Vinyls, LP*, 631 F. Supp. 2d 859, 865 (W.D. Ky. 2009) (finding that one element of nuisance claims is "the reasonableness of the defendant's use of his property"). As to Distributors, Plaintiff's sole theory of unreasonable or unlawful conduct is that Distributors "have unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls

against diversion. . . . Defendants’ failures to create, maintain, and enforce effective controls against diversion include Defendants’ failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.” Compl. ¶ 681. In other words, Plaintiff’s sole theory of unlawful conduct is that Distributors failed to report and refuse suspicious orders. As noted, however, the duties to report and refuse suspicious orders arise out of the federal CSA and its implementing regulations, and there is no analogous state law duty to halt shipments. Thus, to establish its public nuisance claim *as pled*, Plaintiff must show that that Distributors violated the CSA. The claim therefore necessarily raises a federal issue.

The same holds true for Plaintiff’s negligence claim (Count B). In pleading negligence, Plaintiff alleges that defendants “knowingly and intentionally breached their duty to monitor—to identify, report, and prevent suspicious orders.” Compl. ¶ 719. And again, Plaintiff’s cited basis for the alleged duties to report and prevent shipments of suspicious orders includes the federal CSA and DEA guidance. *See supra* at 14. Thus, to establish negligence as pled, Plaintiff must show that Distributors violated their alleged legal obligations under the CSA.

In short, Plaintiff’s purported state law causes of action hinge on its allegations that Distributors breached duties arising out of the federal CSA and its implementing regulations. To determine whether Distributors breached those duties, a court would need to interpret and apply the CSA. Plaintiff’s claims therefore necessarily raise federal issues.

B. The parties “actually dispute” the federal issue.

The federal issues raised by the Complaint are “actually disputed” because the parties contest whether the CSA and its implementing regulations in fact give rise to duties to report and halt suspicious orders for prescription opioids, the precise scope and contours of any such duties that might exist under the CSA, and whether Distributors violated these alleged duties by failing to report and halt suspicious orders. Because Plaintiff’s claims against Distributors depend on

their theory that Distributors breached these alleged duties, this issue is the “central point of dispute.” *Gunn*, 568 U.S. at 259. Indeed, the Complaint recognizes this dispute (at least in part), alleging that “Wholesale Distributor Defendants have refused to recognize any duty beyond reporting suspicious orders.” Compl. ¶ 461.

This dispute also presents a nearly pure question of law. In assessing whether Distributors breached duties arising out of the CSA, the Court must determine not only Distributors’ conduct, but also whether that conduct falls within the scope of the CSA and any alleged duties arising under the CSA. That is, the Court must examine “the contours of [the] federal duty,” “the scope of that duty,” and “whether [Distributors’ conduct] amounted to a breach of that duty.” *NASDAQ*, 770 F.3d at 1023. That analysis will require the Court to determine whether the CSA and its implementing regulations in fact give rise to the duties to report and halt suspicious orders, what any such duties entail, what constitutes a “suspicious” order under the CSA’s implementing regulations, what actions should have been taken to resolve those suspicions or “halt” the shipment, whether existing processes satisfy federal reporting guidelines, and other disputes arising under federal regulations.

Distributors deny that the alleged duties under the CSA are as broad in scope as Plaintiff alleges they are, and further deny that they violated their duties under the CSA in the manner alleged in Plaintiff’s Complaint. Unless Plaintiff concedes both points, the federal issue is actually disputed.

C. The federal issues are “substantial.”

The Supreme Court has explained that “[t]he substantiality inquiry under *Grable* looks . . . to the importance of the issue to the federal system as a whole.” *Gunn*, 568 U.S. at 260. A federal issue “can be important for many reasons,” including because (i) “state adjudication would undermine the development of a uniform body of federal law”; (ii) “resolution of the issue

has broad significance for the federal government”; or (iii) “the case presents a nearly pure issue of law that would have applications to other federal cases.” *Bd. of Comm’rs of Se. La. Flood Prot. Auth.-E. v. Tenn. Gas Pipeline Co.*, 850 F.3d 714, 724 (5th Cir. 2017) (alterations and quotation marks omitted). All three of those factors supports the exercise of federal-question jurisdiction here.

1. There is a federal interest in ensuring uniform interpretation of the CSA.

Courts have often found federal issues sufficiently substantial where they raise “questions [that] involve aspects of . . . complex federal regulatory scheme[s] . . . as to which there is a serious federal interest in claiming the advantages thought to be inherent in a federal forum.” *Broder*, 418 F.3d at 195 (quotation marks omitted). Such rulings are especially common where, as here, federal agencies are responsible for implementing a national regulatory system for which uniformity is essential. In *NASDAQ*, for example, the Second Circuit ruled that “the disputed federal issue in th[e] case—whether [the defendant] violated its Exchange Act obligation to provide a fair and orderly market in conducting an IPO—is sufficiently significant to the development of a uniform body of federal securities regulation to satisfy the requirement of importance to the federal system as a whole.” 770 F.3d at 1024 (quotation marks omitted). Likewise, in *Jacobson*, the Second Circuit held that “minimizing uncertainty over the tax treatment of mortgage-backed securities, as Congress intended, fully justif[ied] resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.” 824 F.3d at 318.

Similarly, Plaintiff’s claims would require this Court to determine the existence and scope of Distributors’ obligations under the CSA and whether Distributors breached those duties, implicating the uniformity concerns addressed above. Regulation of controlled substances is first and foremost federal regulation. In enacting the CSA, Congress stated that it was “providing the

legitimate drug industry with a *unified* approach to narcotic and dangerous drug control.” H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4572 (emphasis added). Plaintiff’s claims thus “involve aspects of the complex federal regulatory scheme applicable to” the national prescription drug supply chain, *Broder*, 418 F.3d at 195, and are “sufficiently significant to the development of a uniform body of [controlled substances] regulation to satisfy the requirement of importance to the federal system as a whole,” *NASDAQ*, 770 F.3d at 1024 (quotation marks omitted). Furthermore, “minimizing uncertainty over” reporting and shipping obligations under the CSA “justifies resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.” *Jacobson*, 824 F.3d at 317–18 (quotation marks and alteration omitted).

Resort to a federal forum is particularly warranted here because Plaintiff’s action is but one of more than 2,300 cases pending nationwide, most of which are in the MDL. If this case is allowed to proceed in federal court and transferred to the MDL, the MDL court will be able to ensure uniform construction and application of the CSA and any alleged duties arising under the CSA, thus achieving Congress’s goal of a “unified approach” to regulating controlled substances. If, on the other hand, this case were remanded to state court, nothing would prevent that court from construing and applying federal CSA obligations in a manner inconsistent with the MDL court and with federal policy.

2. The federal issues presented in this case have broad significance for the federal government.

The federal government has made clear that the opioid litigation will affect its ability to enforce the CSA. Most notably, the Department of Justice filed a Statement of Interest on behalf of the United States in the MDL proceedings, asserting the federal government’s interests in, among other things, its “law enforcement and legal activities in conjunction . . . with the

multidistrict litigation,” specifically including “[c]riminal and civil tools available *under the Controlled Substances Act*.” *In re: Nat’l Prescription Opiate Litig.*, No. 1:17-md-02804 (N.D. Ohio Mar. 1, 2018), ECF No. 161, at 7 (attached as **Exhibit 4**) (emphasis added).

Allowing a state court to resolve state law claims premised on violations of the CSA—and to determine the existence and scope of any duties under the CSA—creates the potential for inconsistent interpretations of the CSA across jurisdictions. *See* 21 U.S.C. § 903 (although Congress did not intend to “occupy the field” of controlled substances regulation with CSA, CSA pre-empts inconsistent state law). Allowing state courts to issue conflicting interpretations of the CSA would inevitably undermine the federal government’s efforts to enforce the statute and sow confusion among federally regulated entities.

3. This case presents a nearly pure issue of law that would have applications to other federal cases.

As noted, this case would require a court to determine the existence of duties arising under the CSA, the scope and contour of any such duties that exist, and “whether [Distributors’ conduct] amounted to a breach of that duty.” *NASDAQ*, 770 F.3d. at 1023. These questions present “nearly pure issue[s] of law” that would necessarily “have applications to other federal cases.” *Tenn. Gas Pipeline*, 850 F.3d at 724. Indeed, these issues apply to the hundreds of actions pending in the MDL, including a host of cases originally filed in or removed to federal courts in Kentucky. *See supra* n.2.

D. Federal jurisdiction will not disrupt the Congressionally approved balance of federal-state judicial responsibilities.

Finally, the federal issues presented by Plaintiff’s Complaint are capable of resolution in federal court “without disrupting the federal-state balance approved by Congress.” *Gunn*, 568 U.S. at 258. Federal courts exclusively hear challenges to DEA authority to enforce the

federal CSA against distributors.⁵ Similarly, federal courts have exclusive jurisdiction over proceedings seeking to enjoin violations of the CSA. *See* 21 U.S.C. § 882(a) (“The district courts of the United States and all courts exercising general jurisdiction in the territories and possessions of the United States shall have jurisdiction in proceedings . . . to enjoin violations of this subchapter.”). Thus, federal courts are already the exclusive fora for determining the permissible scope of restraints on Distributors under the federal CSA. Plaintiff’s Complaint presents these precise questions and, furthermore, expressly seeks injunctive relief. *See* Compl. ¶ 24 (seeking “injunctive relief”).

IV. THE REMAND DECISIONS PLAINTIFF CITES ARE DISTINGUISHABLE AND THE MDL COURT HAS NOT REJECTED MCKESSON’S ASSERTED GROUND FOR REMOVAL.

Plaintiff cites a number of nonbinding and inapposite district court decisions in an attempt to evade federal jurisdiction. Remand Mot. at 10-13. To begin with, Plaintiff cites to an order from the MDL court, *In re Nat’l Prescription Opiate Litig.*, 2019 WL 180246 (N.D. Ohio Jan. 14, 2019), that Judge Polster *withdrew as moot* within days of its filing. *See In re Nat’l Prescription Opiate Litig.*, No. 1:18-op-46311 (N.D. Ohio Jan. 17, 2019), ECF No. 15 (attached as **Exhibit 5**). That order is thus of no legal effect. *E.g.*, *United States v. Sigma Int’l, Inc.*, 300 F.3d 1278, 1280 (11th Cir. 2002) (“[Vacated opinions] are officially gone. They have no legal effect whatever. They are void. None of the statements made in either of them has any remaining force and cannot be considered to express the view of th[e] [issuing] Court.”).

Moreover, many of the cases Plaintiff cites involved allegations of state-law statutory

⁵ *See, e.g., PDK Labs. Inc. v. U.S. Drug Enf’t Admin.*, 362 F.3d 786 (D.C. Cir. 2004) (challenge to DEA program enforcing CSA to prevent diversion of ephedrine); *In Re Admin. Subpoena Walgreen Co. v. U.S. Drug Enf’t Admin.*, 913 F. Supp. 2d 243 (E.D. Va. 2012) (resolving registrant’s motion to require DEA to return subpoenaed documents); *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012) (challenge under Administrative Procedure Act to DEA order suspending registration of distribution facility).

violations not present in this case. The plaintiff in each of those cases alleged that the defendant had violated duties arising not only out of the federal CSA, but also out of the uniform controlled substances act specific to the state in which the case was filed. By contrast, Plaintiff relies *exclusively* on alleged violations of the federal CSA, and does not specifically cite independent state-law statutory requirements to support its allegations that Distributors breached legal duties to halt suspicious orders.

Finally, Plaintiff ignores that multiple courts conducting preliminary assessments of the same jurisdictional issue have concluded that defendants' bases for removal are plausible or, at a minimum, present legally and factually difficult issues. *See, e.g., Portland v. Purdue Pharma LP*, No. 2:18-cv-00282 (D. Me. Nov. 28, 2018), ECF No. 96 ("Defendants have asserted a plausible basis for removal[.]"); *Melrose Park v. McKesson Corp.*, No. 1:18-cv-05288 (N.D. Ill. Aug. 10, 2018), ECF No. 26 ("Preliminary assessment of the jurisdictional issues suggest that they are legally and factually difficult[.]"); *Osage Cty. v. Purdue Pharma LP*, No. 4:18-cv-00461 (N.D. Okla. Nov. 14, 2018), ECF No. 87 ("A preliminary assessment of the jurisdictional issues in this case suggests that they are not straightforward."). As one court concluded in staying proceedings in an action removed on the same grounds as this case: "at first blush, jurisdiction does not appear to be lacking in this case," and "the existence of these difficult questions of jurisdiction weigh in favor of their resolution by one court making similar rulings in hundreds of similar cases." *Seminole Cty. v. Purdue Pharma LP*, No. 6:18-cv-00372 (E.D. Okla. Apr. 3, 2019), ECF No. 51.

At most, Plaintiff's citations to various remand opinions underscore the need to allow the MDL court to address Plaintiff's motion, so as to ensure as much uniformity as possible in the treatment of the remand issues these cases raise.

V. THE COURT SHOULD DEFER CONSIDERATION OF PLAINTIFF'S REMAND MOTION.

The Court may and should defer ruling on Plaintiff's remand motion altogether. As Distributors further explain in their companion motion to stay these proceedings, although federal jurisdiction is proper here, delaying consideration of Plaintiff's remand motion until the JPML makes a final transfer decision will promote judicial efficiency and ensure consistent remand rulings by allowing the MDL court in the Northern District of Ohio to consider this and all other remand motions presenting similar issues.

CONCLUSION

For the reasons set forth above, McKesson respectfully requests that the Court deny Plaintiff's motion to remand.

November 18, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 18 2019, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which sent notification of such filing to all counsel of record.

/s/ Carolyn Purcell Michener
Counsel for McKesson Corporation

EXHIBIT 1

**UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION**

**IN RE: NATIONAL PRESCRIPTION OPIATE
LITIGATION**

MDL No. 2804

(SEE ATTACHED SCHEDULE)

CONDITIONAL TRANSFER ORDER (CTO –114)

On December 5, 2017, the Panel transferred 62 civil action(s) to the United States District Court for the Northern District of Ohio for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* 290 F.Supp.3d 1375 (J.P.M.L. 2017). Since that time, 1,776 additional action(s) have been transferred to the Northern District of Ohio. With the consent of that court, all such actions have been assigned to the Honorable Dan A. Polster.

It appears that the action(s) on this conditional transfer order involve questions of fact that are common to the actions previously transferred to the Northern District of Ohio and assigned to Judge Polster.

Pursuant to Rule 7.1 of the Rules of Procedure of the United States Judicial Panel on Multidistrict Litigation, the action(s) on the attached schedule are transferred under 28 U.S.C. § 1407 to the Northern District of Ohio for the reasons stated in the order of December 5, 2017, and, with the consent of that court, assigned to the Honorable Dan A. Polster.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Northern District of Ohio. The transmittal of this order to said Clerk shall be stayed 7 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 7–day period, the stay will be continued until further order of the Panel.

FOR THE PANEL:



John W. Nichols
Clerk of the Panel

**IN RE: NATIONAL PRESCRIPTION OPIATE
LITIGATION**

MDL No. 2804

SCHEDULE CTO-114 – TAG-ALONG ACTIONS

<u>DIST</u>	<u>DIV.</u>	<u>C.A.NO.</u>	<u>CASE CAPTION</u>
DELAWARE			
DE	1	19-01749	City of Dover et al v. Purdue Pharma L.P. et al
FLORIDA MIDDLE			
FLM	6	19-01841	City of Apopka, Florida v. Endo Health Solutions Inc. et al
KENTUCKY EASTERN			
KYE	3	19-00067	Henderson, City of v. Purdue Pharma L.P. et al
KYE	3	19-00068	Hardin County Fiscal Court et al v. Purdue Pharma L.P. et al
MISSOURI EASTERN			
MOE	4	19-02633	Kuepfer v. Mallinckrodt PLC et al
MOE	4	19-02634	Parrot v. Mallinckrodt PLC et al
MOE	4	19-02640	Robertson v. Mallinckrodt PLC et al
MOE	4	19-02641	Horr v. Mallinckrodt PLC et al
PENNSYLVANIA EASTERN			
PAE	2	19-04438	ADAMS COUNTY v. PURDUE PHARMA L.P. et al
TEXAS SOUTHERN			
TXS	4	19-03580	County of Jim Wells v. CVS Pharmacy, Inc.

EXHIBIT 2

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
FRANKFORT DIVISION

HARDIN COUNTY FISCAL COURT, ON	
BEHALF OF HARDIN COUNTY;	
BRECKINRIDGE COUNTY FISCAL	
COURT, ON BEHALF	
<u>CITY OF HENDERSON, KENTUCKY,</u>	
BRECKINRIDGE COUNTY;	
GREEN COUNTY FISCAL COURT, ON	
BEHALF OF GREEN COUNTY;	
MEADE COUNTY FISCAL COURT, ON	
BEHALF OF MEADE COUNTY;	
OHIO COUNTY FISCAL COURT, ON	No. 3:19-cv-00068-GFV
BEHALF OF OHIO COUNTY;	
ON BEHALF OF THEMSELVES AND	
ALL OTHER SIMILARLY SITUATED	
KENTUCKY COUNTIES (FISCAL	
COURTS),	FIRST AMENDED
<u>HOME RULE CITIES,</u>	CLASS ACTION COMPLAINT
PLAINTIFFS,	
v.	<i>Jury Trial Requested</i>
PURDUE PHARMA L.P.; PURDUE	
PHARMA INC.; PURDUE FREDERICK	
COMPANY; RHODES	
TECHNOLOGIES; RHODES	No. 3:19-cv-00067-GFV
TECHNOLOGIES INC.; RHODES	
PHARMACEUTICALS L.P.; RICHARD	
SACKLER; BEVERLY SACKLER;	
DAVID SACKLER; ILENE SACKLER	
LEFCOURT; JONATHAN SACKLER;	FIRST AMENDED
KATHE SACKLER; MORTIMER D.A.	CLASS ACTION COMPLAINT
SACKLER; THERESA SACKLER;	
ABBOTT LABORATORIES; ABBOTT	<i>Jury Trial Requested</i>
LABORATORIES, INC.; TEVA	
PHARMACEUTICAL INDUSTRIES,	
LTD.; CEPHALON, INC.; TEVA	
PHARMACEUTICALS USA, INC.;	
ALLERGAN PLC; ACTAVIS PLC;	
WATSON PHARMACEUTICALS, INC.;	
WATSON LABORATORIES, INC.;	
ACTAVIS PHARMA, INC.; ACTAVIS	
LLC; ENDO HEALTH SOLUTIONS	
INC.; ENDO PHARMACEUTICALS	
INC.; ENDO INTERNATIONAL PLC;	

<u>PAR PHARMACEUTICAL, INC.; PAR</u>	1256
<u>PHARMACEUTICALS COMPANIES,</u>	
<u>INC.; MALLINCKRODT PLC;</u>	
<u>MALLINCKRODT LLC; SPECGX LLC;</u>	
<u>JOHNSON & JOHNSON; JANSSEN</u>	
<u>PHARMACEUTICALS, INC.;</u>	
<u>NORAMCO, INC.; AMNEAL</u>	
<u>PHARMACEUTICALS, LLC; AMNEAL</u>	
<u>PHARMACEUTICALS, INC.; MYLAN</u>	
<u>PHARMACEUTICALS, INC.; WEST-</u>	

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TABLE OF CONTENTS

Procedural Statement	1
Introduction	1
A. Kentucky’s Opioid Crisis—Epidemic.	1
B. The National Opioid Crisis—Epidemic.	5
C. This Lawsuit and the Plaintiffs’—Kentucky Counties <u>Home Rule Cities</u>—Claims.	6
1. The Opioid Manufacturers.	7
2. The Distributors and Pharmacies— the Suppliers.	9
3. The Kentucky Governmental Defendants.	10
Jurisdiction & Venue	11
Parties.	12
A. Plaintiffs—Kentucky Fiscal Courts <u>Home Rule Cities</u>.	12
B. Defendants.	1413
1. Manufacturing (“Marketing”) Defendants.	15 14
a. Purdue Entities.	15 14
b. Rhodes Entities.	16 15
c. Sackler Defendants.	18 17
d. Abbott Entities.	23 22
e. Teva Entities.	25 24
f. Allergan Entities.	27 26
g. Endo Entities.	29 28
h. Mallinckrodt Entities.	30 29
i. Johnson & Johnson Entities.	32 31
j. Amneal Entities.	35 34
k. Mylan.	35 34

l.	West-Ward.	3635
m.	KVK-Tech.	3635
n.	Assertio Entities.	3736
2.	Wholesale Distributor Defendants.	3736
a.	AmerisourceBergen Entities	3837
b.	Anda.	3938
c.	Cardinal Health.	3938
d.	CVS.	4039
e.	Kroger.	4039
f.	McKesson.	4140
g.	Rite Aid Corp.	4241
h.	Smith Drug.	4241
i.	Walgreens.	4241
j.	Walmart.	4342
3.	Retail Pharmacy Defendants.	4342
a.	CVS Pharmacy.	4443
b.	Fred's Stores.	4443
c.	Kroger.	4443
d.	Rite Aid KY.	4544
e.	Walgreens.	4544
f.	Walmart.	4544
C.	State Government Defendants.	4645
	Factual Background.	4645
A.	The Opioid Epidemic.	4645
1.	The National Opioid Epidemic.	4645

2. Kentucky’s Opioid Epidemic. ~~51~~50

B. The Manufacturer (“Marketing”) Defendants’ False, Deceptive, and Illicit Marketing of Opioids. ~~52~~51

1. The Manufacturer (“Marketing”) Defendants Used Multiple Avenues to Disseminate Their False and Deceptive Statements about Opioids. ~~55~~54

a. Direct Marketing. ~~56~~55

b. Indirect Marketing. ~~58~~57

2. The Manufacturer (“Marketing”) Defendants’ Coordinated Marketing Scheme Misrepresented the Significant Risks of Opioids. ~~70~~69

a. The Manufacturer (“Marketing”) Defendants engaged in a coordinated campaign of false, deceptive, and unfair assurances grossly understating and misstating the dangerous addiction risks of the opioid drugs. ~~70~~69

b. The Manufacturer (“Marketing”) Defendants engaged in a coordinated campaign of false, deceptive, and unfair assurances grossly overstating the benefits of the opioid drugs. ~~79~~78

3. The Manufacturer (“Marketing”) Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations. ~~86~~85

4. The Manufacturer (“Marketing”) Defendants made Materially Deceptive Statements and Concealed Material Facts. ~~87~~86

5. The Manufacturer (“Marketing”) Defendants Fraudulently Concealed Their Misconduct. ~~94~~93

C. The Wholesale Distributor Defendants’ Unlawful Sale and Distribution of Opioids. ~~97~~95

1. Wholesale Distributor Defendants’ Have a Duty to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders. ~~98~~97

2. The Wholesale Distributor Defendants Breached their Legal Duties. ~~105~~104

3. The Wholesale Distributor Defendants Actively Avoided, and Willfully Misrepresented their Compliance with, their Legal Duties. ~~107~~106

D. The Manufacturer (“Marketing”) Defendants Unlawful Failure to Prevent Diversion and Failure to Monitor, Report, and Prevent Suspicious Orders.

E. All Defendants Engaged in Unlawful Conduct and Breached their Legal Duties thereby Causing the Harm and Substantial Damages Alleged Herein.

~~117~~116

F. The Retail Pharmacy Defendants Were on Notice of and Contributed to the Illegal Diversion of Prescription Opioids.

~~119~~118

1. The Retail Pharmacy Defendants Have a Duty to Prevent Diversion

~~120~~119

2. Multiple Enforcement Actions against the Retail Pharmacy Defendants Confirms their Compliance Failures.

~~124~~123

a. CVS.

~~124~~123

b. Walgreens.

~~127~~126

c. Rite Aid.

~~129~~128

G. The Opioid (“Marketing”) Defendants Colluded and Conspired in the Marketing, Promotion, Distribution, Sale, and Dispensing of Opioids.

~~131~~130

1. The Opioid Conspiracy’s Purpose—Increased Sales & Profit.

~~131~~130

2. The Opioid Marketing Conspiracy.

~~136~~135

3. The Opioid (“Marketing”) Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use.

~~140~~139

4. Additional Evidence of the Opioid Conspiracy.

~~141~~140

- H. The Manufacturer and Distributer (“Opioid Supply”) Defendants Colluded and Conspired in the Marketing, Promotion, Distribution, Sale, and Dispensing of Opioids.

~~144~~143

- I. The State Governmental Defendants failed to fulfill their statutory obligations to police and regulate the manufacture, marketing, distribution, sale and dispensing of opioids.

~~155~~154

Class Allegations

~~156~~155

Claims for Relief

~~158~~157

- A. Public Nuisance (All Defendants, excl. State Governmental Defendants)...

~~158~~157

- B. Negligence (All Defendants, excl. State Governmental Defendants).

~~168~~167

- C. Negligence *Per Se*—Statutory Reporting Violation (All Defendants, excl. State Governmental Defendants).

~~169~~168

D.	Negligence <i>Per Se</i> -- False Advertising Violation (Opioid (“Marketing”) Defendants and Opioid Supply Defendants).	171 <u>170</u>
E.	Negligent Misrepresentation (All Defendants, excl. State Governmental Defendants).	172 <u>171</u>
F.	Civil Conspiracy (Opioid (“Marketing”) Defendants).	174 <u>173</u>
G.	Civil Conspiracy (Opioid Supply Defendants).	175 <u>174</u>
H.	Consumer Protection (All Defendants, excl. State Governmental Defendants).	176 <u>175</u>
I.	Fraud by Omission (All Defendants, excl. State Governmental Defendants).	178 <u>177</u>
J.	Unjust Enrichment (All Defendants, excl. State Governmental Defendants).	<u>179</u>
K.	<u>Punitive Damages (All Defendants, excl. State Governmental Defendants).</u>	180
K.	Punitive Damages (All Defendants, excl. State Governmental Defendants).	181
L.	Writ of Mandamus (Kentucky Governmental Defendants).	183 <u>182</u>
M.	Declaratory Relief (Kentucky Governmental Defendants).	183 <u>182</u>
N.	Injunctive Relief (Kentucky Governmental Defendants).	184 <u>183</u>
	Prayer for Relief	184 <u>183</u>
A.	Defendants.	184 <u>183</u>
B.	State Governmental Defendants.	186 <u>185</u>

PROCEDURAL STATEMENT

1. The headings contained in this Class Action Complaint are intended only to assist in reviewing the statements and allegations contained herein. To avoid the unnecessary repetition in each section, the Plaintiffs affirm and incorporate each paragraph in each section of this Class Action Complaint as though fully set forth therein.

2. Despite its length, the factual allegations contained in this Class Action Complaint are *not exhaustive* and are presented throughout this Class Action Complaint solely to provide the Defendants with the requisite notice of the basis for the Plaintiffs' allegations and claims. The Plaintiffs expressly reserve the right to plead additional facts where and as necessary to ensure complete relief. Further, pursuant to CR 15.02, this Class Action Complaint should be deemed to conform with the evidence on which the Plaintiffs' claims are ultimately tried.

INTRODUCTION

A. Kentucky's Opioid Crisis—Epidemic.

3. No state has been hit harder by the opioid epidemic than Kentucky. The opioid epidemic poses an ongoing crisis in Kentucky. The rate of overdose deaths involving opioid prescriptions in Kentucky rose steadily from 1.0 deaths per 100,000 persons in 1999 to 10.2 deaths per 100,000 persons in 2017.

4. According to the CDC, in 2015, Kentucky shared the 2nd highest overdose rate in the country. Data from 2013 onward shows that Kentucky has the 3rd highest drug overdose mortality rate in the country. Between 2012 and 2016, drug overdoses caused a total of 5,822 deaths in Kentucky. In 2017, there were 1,565 fatal drug overdoses in Kentucky, which is an increase to approximately 130 deaths per month. According to the National Institute on Drug Abuse, Kentucky has double the overdose rate of the national average. Drug overdoses have

become the leading cause of accidental death in Kentucky.

5. In 2015, 102 opioid prescriptions were written for every 100 Kentucky residents, which was 1.5 times the national average. Kentucky's overdose fatalities, which were already high, increased dramatically in 2015. Overdose deaths of Kentucky residents, regardless of where the death occurred, and non-residents who died in Kentucky, numbered 1,249 in 2015.

6. In 2015, drug overdoses accounted for 51.17% of Kentucky's statewide accidental deaths, more than motor vehicle accidents, fire, drowning and gunshot wounds combined. In 2015, opioids accounted for 46.63% of the statewide total of drug related fatal overdose victims. In 2016, the number of deaths statewide due to drug overdoses was nearly five-times that of car accidents.

7. Opioid abuse has reached epidemic levels in Kentucky. From February 1, 2016, to January 31, 2017, pharmacies in Kentucky filled prescriptions for 307,234,816 doses of prescription opioids—the equivalent of 69 doses for every man, woman, and child residing in Kentucky.

8. The progression from prescription opioids to the use of illicit drugs, particularly injectable heroin, is well documented, with approximately 75% of heroin users reporting that their initial drug use was through prescription. As Kentucky citizens who become addicted to prescription opioids have predictably migrated to illicit, but less expensive, opioids, namely heroin and fentanyl, overdoses have dramatically increased. The opioid-overdose reversal drug naloxone was administered in four out of every seven Emergency Medical Services runs; and on average, seven response calls per day were to drug-related incidents.

9. Opioids have endangered public health in Kentucky even beyond addiction and overdose. Addicts who are not killed by drug addiction experience a variety of health

consequences (including non-fatal overdoses) and engage in a variety of risky drug-seeking behaviors. Widespread drug addiction imposes costs on the community including health care and substance abuse treatment costs – a substantial portion of which were provided by Plaintiffs – as well as other costs borne by ~~the community~~ their respective cities.

10. Kentucky’s children have been especially vulnerable to the opioid epidemic. Along with overdose deaths, the number and rate of neonatal abstinence syndrome (“NAS”) – a condition suffered by babies born to mothers addicted to opioids – has also increased dramatically in Kentucky. Kentucky has had one of the highest rates of pregnant women using opioids in the country.

11. In 2014, Kentucky had the third-highest rate of pregnant women with opioid use disorder. In just one 12-month period, between August 1, 2014 and July 31, 2015, 1,234 infants in Kentucky were born addicted to opioids, more than 100 newborns per month. The number of NAS cases in Kentucky totaled 1,115 in 2016 based on hospital discharge data. In 2017, the number of babies born with NAS in Kentucky had increased by 375% since 2007.

12. These infants will spend weeks in neonatal intensive care units while they painfully withdraw from the drugs – a process so painful that it traps many adults on opioids. Research has indicated that these children are likely to suffer from continued serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening.

13. The widespread use of opioids and corresponding increases in addiction and abuse have led to increased emergency room visits, emergency responses to overdoses, and emergency medical technicians’ administration of naloxone—an antidote to opioid overdose. In Louisville, the police force administered 123 doses of naloxone in just the first six weeks of

2017— representing approximately three overdoses each day. It also has resulted in dramatic growth in drug-related crimes. There have been increases in domestic violence, robberies, burglaries, and thefts, among other crimes across Kentucky. An estimated 90% of defendants in Floyd County are prosecuted for crimes related to prescription drug abuse or diversion.

14. Kentucky has seen an increase in blood borne diseases caused by intravenous drug use, including hepatitis C (HCV) and human immunodeficiency (HIV). Intravenous use of opioids, which has been a particular problem with easy-to-inject Opana ER, has led to a surge in HCV in the state and created a risk of an even broader epidemic. Kentucky and other states in the central Appalachian region of the country experienced a 364% increase in reported acute HCV among individuals aged 30 years old or below between 2006 and 2012.

15. Among the 220 U.S. counties identified by CDC as the most vulnerable to HIV and HCV infections among people who inject drugs in the context of the national opioid epidemic, 54 were located in Kentucky, including Wolfe County, which had the greatest risk in the United States.

16. Kentucky had the highest rate of new hepatitis C infections in the nation—more than six times the national average—from 2008 through 2015. St. Elizabeth Healthcare in Edgewood reports that it sees up to ten new cases of hepatitis C daily. If untreated, hepatitis C continues to be transmitted, including in childbirth. Hepatitis C can ultimately cause liver cancer, fibrosis, or cirrhosis, and is the leading cause of liver transplants in the country.

17. Over the last decade, eastern Kentucky has lost over 11,000 coal mining jobs, according to the Kentucky Department of Energy. When the mining industry plummeted, other local businesses were also forced to close. The collapse of the coal industry forced many of the town's residents into joblessness and triggered a sense of hopelessness, which exacerbated the

opioid crisis in the region. Abuse of prescription pain medication is especially widespread among the growing ranks of out-of-work miners, who were often prescribed opioid medications to deal with the rigors of the job.

18. Across Kentucky, families and communities face heartbreaking tragedies that cannot be adequately conveyed by statistics, and they have faced them all too often. Many grieving families have been financially tapped out by the costs of repeated cycles of addiction treatment programs; others have lost hope and given up. The increasing number of cases takes both a physical and mental toll on investigators, first-responders, and ultimately the public at large—the Plaintiffs.

B. The National Opioid Crisis—Epidemic.

19. The United States is in the midst of an opioid epidemic caused by the Defendants', *see infra*, collective and individual unlawful marketing, sale, distribution, and dispensing of prescription opioids that has resulted in addiction, criminal activity, serious health issues, and the loss of life.

20. The United States constitutes 4.6% of the world's population but consumed 80% of the world's opioid supply in 2011. According to the Centers for Disease Control and Prevention ("CDC"), from 1999 to 2014, the sales of prescription opioids in the U.S. nearly quadrupled, but there was no overall change in the amount of pain that Americans reported.

21. It is undisputed that opioids are both addictive and deadly. Between 1999 and 2014, more than 165,000 Americans died of opioid overdose. Deaths related to opioids are accelerating. In 2011, the CDC declared that prescription opioid deaths had reached "epidemic levels." That year, 11,693 people died of prescription opioid overdoses. Since then, prescription opioid deaths have more than quadrupled, reaching 47,600 Americans in 2017— more than ten

times the number of Americans who died in the entire Iraq War.

22. According to the CDC, opioid overdoses killed more than 45,000 people, nationally, over a 12-month timeframe that ended in September 2017. It is already the deadliest drug epidemic in American history. If current trends continue, lost lives from opioid overdoses will soon represent the vast majority of all drug overdose deaths in the United States.

23. The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.” In many cases, heroin abuse starts with prescription opioid addiction. An inflated volume of opioids invariably leads to increased diversion and abuse. Indeed, there is a “parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.”

24. For most people who misuse opioids, the source of their drugs can typically be found in the excess supply of drugs in the community, beyond what is needed for legitimate medical purposes. Filling an opioid prescription is a significant risk factor for overdose.

25. According to the CDC, the United States is currently seeing the highest overdose death rate ever recorded. Aside from overdose, long-term opioid use is associated with a significant increase in mortality from other causes. As opioid-related deaths increase, the life expectancy in the United States decreases.

26. On October 28, 2017, the President of the United States declared the opioid crisis a public health emergency.

C. This Lawsuit and the Plaintiffs’—Kentucky ~~Counties~~ Home Rule Cities—Claims.

27. The Plaintiffs, comprised solely of Kentucky ~~Counties~~ Home Rule Cities, bring this lawsuit to eliminate the hazard to public health and safety caused by the opioid (defined as

all opiate

drugs whether natural, synthetic, or semi-synthetic) epidemic, to abate the nuisance caused thereby, and to recoup monies that have been spent because of Defendants' individual and collective false, deceptive and unfair marketing and/or unlawful diversion of prescription opioids. Such economic damages were foreseeable to Defendants and were sustained because of Defendants' wanton, reckless, intentional and/or unlawful actions and omissions. The Plaintiffs also seek relief arising from and related to the governmental Defendants', *see infra*, failure to perform their statutory and regulatory duties.

1. The Opioid Manufacturers.

28. This lawsuit is focused on the primary cause of the opioid crisis: the false and misleading marketing scheme in which the Defendants joined and conspired to dramatically increase the demand for and sale of opioids throughout the Commonwealth of Kentucky.

29. The Defendants who manufacture, market, promote, and sell prescription opioids precipitated this crisis. These opioids have various brand names and generic names, and include OxyContin, fentanyl, hydrocodone, oxycodone, among others. Through a massive marketing campaign premised on false and incomplete information, these Defendants engineered a dramatic shift in how and when opioids are prescribed by the medical community and used by patients.

30. To increase the potency, and corresponding demand for opioids, the Defendants who manufacture opioids sought to first develop a "better" opioid pain-killer—similar to Big Tobacco's spiking the nicotine content in cigarettes, the manufactures spiked the efficacy of the opioids.

31. The manufactures then orchestrated a campaign of misinformation—a relentless and methodical plan to dramatically and exponentially increase their respective sales and profits—to broaden and deepen the market and demand for opioids. This campaign hinged on

convincing the medical community (i) that opioids should be used not just for acute care, but also for chronic pain; and (ii) that opioids were not addictive—they were low risk. This campaign was predicated on a systemic and calculated lie.

32. The manufacturers knew that opioids were not appropriate for long-term use and, more importantly, that they were extremely addictive. Again, the manufacturers sought to benefit from this addictive feature by increasing the efficacy of the opioids—creating a dependent client for life.

33. Studies have found diagnosed opioid dependence rates in primary care settings as high as 26%. Among opioid users who received four prescriptions in a year, 41.3% meet diagnostic criteria for a lifetime opioid-use disorder. Because opioids cause tolerance and dependence, patients who take the drugs for even a short time become a physiologically captured market.

34. According to the U.S. Department of Health and Human Services, more than two million Americans are now opioid-dependent. The difficulty in stopping use is particularly true for patients first prescribed an extended release opioid. Patients who initiated treatment on an extended release opioid – such as OxyContin – have a 27.3% likelihood to be using opioids one year later, and a 20.5% likelihood of using opioids three years later. Whether in the end a patient meets the clinical definition of addiction or is simply dependent and unable to stop using opioids, once opioids are prescribed for even a short period of time, patients are hooked.

35. Opioids pose high risks for children and adolescents. Most of the use in this population is off label because opioids are not approved for children. Use of prescription opioid pain medication before high school graduation is associated with a 33% increase in the risk of later opioid misuse. The misuse of opioids in adolescents strongly predicts the later onset of

heroin use. Nonetheless, the 2016 CDC guidelines found that there have been significant increases in opioid prescribing for children and adolescents, for conditions such as headaches and sports injuries.

36. Again, the manufacturers goal was simple: dramatically increase sales by (i) increasing the potency; and (ii) convincing doctors to prescribe opioids not only for acute pain (e.g. cancer or short-term post-operative pain), but also for common chronic pain (e.g. back pain and arthritis). They did this even though they knew that opioids were highly addictive and subject to abuse, and that their claims regarding the risks, benefits, and superiority of opioids for long-term use were patently false and misleading.

2. The Distributors and Pharmacies– the Suppliers.

37. The opioid distributors and retail pharmacies comprised the suppliers who, recognizing and being driven by the significant profits from the distribution, sale and dispensing of opioids, willfully and knowingly disregarded their duties under Kentucky law—resulting in the flood of opioids throughout the Commonwealth of Kentucky that precipitated the opioid epidemic.

38. The suppliers, through their willingness to uncritically supply whatever quantities of opioids pharmacies ordered and fill prescriptions without scrutiny or hesitation, normalized overprescribing and caused widespread proliferation and availability of these dangerous drugs throughout communities in the Commonwealth.

39. The sharp increase in opioid use resulting from Defendants' conduct has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the Commonwealth.

40. The suppliers' practice of continually filling, and refilling, opioid prescriptions,

including from suspicious prescribers, and failing to report suspicious orders of opioids has enabled an oversupply of opioids to communities throughout the Commonwealth.

41. The suppliers—in particular the distributors—had significant financial incentives to distribute higher volumes of opioids and not to report suspicious orders or guard against diversion. Wholesale drug distributors acquire opioids from the manufacturers at an established wholesale acquisition cost. Discounts and rebates are generally offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors which in turn allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit.

3. The Kentucky Governmental Defendants.

42. Kentucky, as with a number of sovereign states, has enacted significant legislative protections for the state's constituents including, inter alia, the Plaintiffs. The responsibility for enforcing and policing these legislative protections rests *initially* with Kentucky's executive officer—the governor—the Cabinet for Health and Family Services, and the Kentucky Pharmacy Board—whose majority members are appointed by the governor.

43. The governor and, by extension, the Cabinet for Health and Family Services and the Kentucky Pharmacy Board were and remain obligated by statute to control, manage, and supervise the flow of opioids into and throughout the Commonwealth of Kentucky—to carry out their legislatively mandated duties to protect the public.

The regulation of controlled substances in this Commonwealth is important and necessary for the preservation of public safety and public health.¹

* * * * *

¹ KRS 218A.005(1).

The practice of pharmacy within the Commonwealth is declared to be a professional practice affecting the public health, safety, and welfare, and is subject to regulation and control in the public interest.²

44. A necessary and indispensable element in the abatement of Kentucky's Opioid Epidemic, is the enforcement and policing of the manufacture, marketing, distribution, sale, and dispensing of opioids in and throughout the Commonwealth—requiring the Kentucky Governmental Defendants for to perform the legislatively mandated and required duties.

JURISDICTION & VENUE

45. This Court has subject matter jurisdiction over the claims asserted in this lawsuit pursuant to Kentucky Revised Statutes 23A.010. Plaintiffs' claims do *not* fall within Kentucky Revised Statutes 24A.120. The amount in controversy *exceeds* five thousand dollars (\$5,000), exclusive of interest and costs.

46. Venue is proper in this Court. Defendants' individual and collective actions forming the basis for Plaintiffs' claims occurred throughout the Commonwealth of Kentucky, as well as in Franklin County. Defendants' agents are registered with, and located in, Franklin County.

47. This action is not removable to federal court for many reasons, including inter alia: (i) a lack of complete diversity of citizenship; (ii) the claims asserted herein arise solely under Kentucky's laws and regulations; (iii) no claims are asserted under any federal law or regulation, and any inference to the contrary is expressly disavowed; and (iv) the claims asserted herein are solely on behalf of Kentucky ~~Counties—Fiscal Courts~~Home Rule cities—all within the Commonwealth of Kentucky.

² KRS 315.002.

This action is similarly *not* removable to federal court under the Class Action

Fairness Act for many reasons, including, inter alia: (i) the class is comprised of *less than* 100

Kentucky ~~Counties (Fiscal Courts)~~ Home Rule cities; (ii) *more than* two-thirds—in fact all—of the Plaintiffs are

Kentucky citizens; (iii) the Plaintiffs seek significant relief from *no less than* three (3)

Defendants who are Kentucky citizens and whose conduct—individually and collectively—occurred in Kentucky and form the basis of Plaintiffs’ claims—also asserted under Kentucky law.

48. Both general and personal jurisdiction apply to each Defendant named herein. Each Defendant purposely availed themselves of the privilege of seeking and doing business in the Commonwealth of Kentucky—reaping billions of dollars in profits at the expense of the Plaintiffs. Given the foregoing, as well as the Defendants’ respective obligations to comply with Kentucky’s licensing and permit requirements for the manufacture, distribution, sale, and dispensing of opioids, Defendants should have anticipated being “haled” into this Court to answer for their illicit and improper activities.

PARTIES

A. Plaintiffs—Kentucky ~~Fiscal Courts~~ Home Rule Cities.

49. Plaintiff ~~Hardin County Fiscal Court~~ (“~~Hardin County~~ City of Henderson, Kentucky (“Henderson”)”) is a Kentucky Home Rule City governmental entity authorized, and entrusted with, protecting the public health, safety, and welfare of its residents. ~~Hardin County~~ See e.g. KRS 81.005(1). As a Home Rule city, Henderson’s mandate includes asserting and pursuing all available relief for the claims asserted in this lawsuit relating to Defendants’ individual and collective actions in their improper, reckless, willful, and wanton distribution of opioid drugs throughout ~~Hardin County, as well as throughout the Commonwealth of Kentucky~~ Henderson.

~~51. Plaintiff Breckinridge County Fiscal Court (“Breckinridge County”) is a~~

~~Kentucky governmental entity authorized, and entrusted with, protecting the public health,~~

~~safety, and welfare of its residents. Breckinridge County’s mandate includes asserting and pursuing all available relief for the claims asserted in this lawsuit relating to Defendants’ individual and collective actions in their improper, reckless, willful, and wanton distribution of opioid drugs throughout Breckinridge County, as well as throughout the Commonwealth of Kentucky.~~

~~52. Plaintiff Green County Fiscal Court (“Green County”) is a Kentucky governmental entity authorized, and entrusted with, protecting the public health, safety, and welfare of its residents. Green County’s mandate includes asserting and pursuing all available relief for the claims asserted in this lawsuit relating to Defendants’ individual and collective actions in their improper, reckless, willful, and wanton distribution of opioid drugs throughout Green County, as well as throughout the Commonwealth of Kentucky.~~

~~53. Plaintiff Meade County Fiscal Court (“Meade County”) is a Kentucky governmental entity authorized, and entrusted with, protecting the public health, safety, and welfare of its residents. Hardin County’s mandate includes asserting and pursuing all available relief for the claims asserted in this lawsuit relating to Defendants’ individual and collective actions in their improper, reckless, willful, and wanton distribution of opioid drugs throughout Meade County, as well as throughout the Commonwealth of Kentucky.~~

~~54. Plaintiff Ohio County Fiscal Court (“Ohio County”) is a Kentucky governmental entity authorized, and entrusted with, protecting the public health, safety, and welfare of its residents. Ohio County’s mandate includes asserting and pursuing all available relief for the claims asserted in this lawsuit relating to Defendants’ individual and collective actions in their improper, reckless, willful, and wanton distribution of opioid drugs throughout Ohio County, as well as throughout the Commonwealth of Kentucky.~~

50. ~~55. Plaintiffs bring~~Henderson brings this action on ~~their~~its behalf, and on behalf of all other Kentucky ~~Counties (Fiscal Courts)~~

Home Rule cities (collectively the “**Plaintiffs**”). *See e.g.* CR 23. The Plaintiffs ~~includes~~include all similarly situated Kentucky ~~Counties (Fiscal Courts)~~Home Rule cities with populations in exceeding four thousand (4,000), and who have not filed a civil action and/or do not have a civil action pending in the National Prescription Opiate Litigation MDL 2804.³

51. ~~56.~~ Plaintiffs have declared that opioid abuse, addiction, morbidity and mortality has created a serious and significant public health and safety crisis, and is a public nuisance, and that the diversion of legally produced controlled substances into the illicit market caused or contributed to this public nuisance, both in the past and continuing into the foreseeable future. The distribution and diversion of opioids into and throughout the Commonwealth of Kentucky, and into Plaintiffs’ respective ~~county and the surrounding areas~~city, created this foreseeable opioid crisis and opioid public nuisance for which Plaintiffs seek all available relief.

B. Defendants.

52. ~~57.~~ All of the actions described herein were part of, and in furtherance of, the unlawful manufacture, promotion, marketing, distribution, sale, and dispensing of opioids throughout the Commonwealth of Kentucky, and were:

- authorized, ordered, and/or performed by Defendants’ respective alter-egos, subsidiaries, officers, agents, employees, or other representatives while actively engaged in the management of Defendants’ affairs within the course and scope of their duties and employment; and/or
- with Defendants’ respective actual, apparent, and/or ostensible authority.

~~58.~~ The true name, identity, and capacity of Defendants’ respective alter-egos, subsidiaries, officers, agents, employees, or other representatives, including and capacities, whether individual, corporate, associate, are presently unknown to Plaintiff and the Plaintiff

³ Plaintiffs’ proposed class definition is provided further herein.

Class (collectively the “Plaintiffs”). Plaintiffs therefore reserve the right to amend this complaint where, and as, necessary to obtain full and complete relief for their claims from all those responsible.

1. Manufacturing (“Marketing”) Defendants.

53. ~~59.~~ The Manufacturing (“Marketing”) Defendants are defined below. At all relevant times, the Manufacturing (“Marketing”) Defendants have manufactured, promoted, marketed, distributed, and sold opioids throughout the Commonwealth of Kentucky—activities which have failed to comply with their legal obligations to their patients and to the public at large.

a. Purdue Entities.

54. ~~60.~~ Defendant **Purdue Pharma L.P.** is a limited partnership organized under the laws of the State of Delaware with its principal place of business in Connecticut.

55. ~~61.~~ Defendant **Purdue Pharma Inc.** is a New York corporation with its principal place of business in Stamford, Connecticut, and is the general partner of Purdue Pharma, L.P.

56. ~~62.~~ Defendant **Purdue Frederick Company** is a Delaware corporation with its principal place of business in Connecticut.

57. ~~63.~~ Defendants Purdue Pharma L.P., Purdue Pharma Inc., and the Purdue Frederick Company (collectively the “**Purdue Entities**”) acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

~~64.~~ At all relevant times, the Purdue Entities manufactured prescription opioids, including OxyContin, MS Contin, Dilaudid, Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, which were in turn promoted, marketed, distributed, and sold throughout the Commonwealth of Kentucky.

58. ~~65.~~ OxyContin is the Purdue Entities’ best-selling opioid. Since 2009, Purdue’s

annual nationwide sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion—reflecting a 350% increase from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

59. ~~66.~~ In furtherance of their opioid promotions, marketing, and resulting sales, the Purdue Entities made thousands of payments to physicians nationwide, including in the Commonwealth of Kentucky, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, many of whom were not oncologists and did not treat cancer pain, but in fact to deceptively promote and maximize the use of opioids—to manipulate the market thereby increasing their corresponding sales and resulting profits.

60. ~~67.~~ The Purdue Entities' misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

b. Rhodes Entities.

61. ~~68.~~ Defendant **Rhodes Technologies** ("Rhodes Tech") is a Delaware general partnership formed on April 12, 2005 with its principal place of business in Coventry, R.I. At relevant times, Rhodes Tech or its predecessor has manufactured and supplied Purdue with oxycodone, the active pharmaceutical ingredient in OxyContin, for use in the manufacture of pharmaceutical preparations.

~~69.~~ Defendant **Rhodes Technologies Inc.** ("RTI") is a Delaware corporation formed January 28, 1999 with its principal place of business in Coventry, Rhode Island. RTI is a general partner of Rhodes Tech. At relevant times, RTI has manufactured and supplied Purdue with oxycodone, the active pharmaceutical ingredient in OxyContin, for use in the manufacture of

pharmaceutical preparations or has managed Rhodes Tech or its predecessor in doing so.

62. ~~70.~~ Defendant **Rhodes Pharmaceuticals L.P.** (“Rhodes Pharma”) is a Delaware limited partnership formed on November 9, 2007 with its principal place of business in Coventry, Rhode Island.

63. ~~71.~~ Defendants Rhodes Tech, RTI, and Rhodes Pharma (collectively the “**Rhodes Entities**”) acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

64. ~~72.~~ At all relevant times, Rhodes Pharma has marketed a generic form of OxyContin which is manufactured by Purdue Pharmaceuticals L.P. (“PPNC”), a Delaware limited partnership, which is a subsidiary of Defendant PPLP and which owns and operates a pharmaceutical manufacturing facility in Wilson, North Carolina.

65. ~~73.~~ At all relevant times, the Rhodes Entities manufactured a generic form of OxyContin, which was in turn promoted, marketed, distributed, and sold throughout the Commonwealth of Kentucky.

66. ~~74.~~ In furtherance of its opioid promotions, marketing, and resulting sales, the Rhodes Entities made thousands of payments to physicians nationwide, including in the Commonwealth of Kentucky, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids—to manipulate the market thereby increasing their corresponding sales and resulting profits.

~~75.~~ The Rhodes Entities’ misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

c. **Sackler Defendants.**

67. ~~76.~~ The following Defendants, all members of the Sackler family that beneficially own Purdue, have served on the Board of Purdue and directed the activities of Purdue during the relevant times as follows:

- **Richard Sackler** (all relevant times until 2018), a resident of Florida;
- **Beverly Sackler** (all relevant times until 2017), a resident of Connecticut;
- **David Sackler** (2012-18), a resident of New York;
- **Ilene Sackler Lefcourt** (all relevant times), a resident of New York;
- **Jonathan Sackler** (all relevant times), a resident of Connecticut;
- **Kathe Sackler** (all relevant times), a resident of Connecticut;
- **Mortimer D.A. Sackler** (all relevant times), a resident of New York; and
- **Theresa Sackler** (all relevant times until 2018), a resident of the United Kingdom.

68. ~~77.~~ The foregoing Defendants (collectively, the “**Sackler Defendants**”) controlled, directed, and were responsible for Purdue’s misconduct as detailed in this complaint. Each of them willingly accepted and took a seat on the Board of Directors of Purdue Pharma Inc. Based on their active and coordinated efforts, the Sackler Defendants held the controlling majority of the Board of Directors of Purdue Pharma Inc.

~~78.~~ The Sackler Defendants’ control of Purdue’s Board also provided them with full power and control over Purdue Pharma Inc. and Purdue Pharma L.P. The Sackler Defendants exercised their complete control to direct and to orchestrate a systemically deceptive sales and marketing plan to exponentially increase the sale of opioids—e.g. OxyContin manufactured by the Purdue entities, and its generic version manufactured by the Rhodes entities.

69. ~~79.~~ The Sackler Defendants' complete direction and control—of the Purdue Entities and the Rhodes Entities—included overseeing and directing the actions of executives and sales employees. From the money the Purdue Entities and the Rhodes Entities Purdue gleaned from their deceptive promotional, marketing, and sales initiatives, the Sackler Defendants reaped billions of dollars in personal profits.

70. ~~80.~~ The Sackler Defendants, at all pertinent times, constituted a majority of the Board, which gave them full power and control over the Purdue Entities and the Rhodes Entities—including control of the minutiae of the daily activities. To be clear, the Sackler Defendants exercised complete control over, and direction in, the Purdue Entities' and the Rhodes Entities' fraudulent manipulation of the public discourse including orchestrating the deceptive promotional, marketing, and sales practices that led to the opioid epidemic—again, for their own personal enrichment at the expense of the Commonwealth of Kentucky.

71. ~~81.~~ While the Sackler Defendants relinquished their officer titles around 2003, they did not relinquish their complete control and orchestrated efforts. They simply sought to shield themselves from future criminal and civil liability for their actions by hiding behind a corporate shell game. Regardless, the Sackler Defendants did not forgo their ownership of the Purdue Entities and the Rhodes Entities—they continued to aggressively pursue their own personal wealth at the expense of the public. To that end, the Sackler Defendants retained full power and complete control of the Purdue Entities and the Rhodes Entities board of directors.

~~82.~~ In furtherance of their greed, and at all relevant times through at least the end of 2018, the Sackler Defendants continued to exercise their complete dominance and control over deceptive promotion, marketing, and sales campaigns for the Purdue Entities and the Rhodes Entities. They directed the hire of hundreds more sales representatives to visit doctors thousands

more times—continuing to knowingly spread misinformation concerning opioid use in a desperate effort to obtain every possible dollar of profit before their fraudulent endeavor was shut-down by civil litigation and/or criminal action.

72. ~~83.~~ Notably, the Sackler Defendants insisted that sales representatives repeatedly visit the most prolific prescribers. They directed sales representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied unlawful tactics to keep patients on opioids longer and then ordered staff to use them. They required staff provide detailed reports about doctors suspected of misconduct, how much money the Purdue Entities and the Rhodes Entities made from them, and how few of them the Purdue Entities and the Rhodes Entities had reported to the authorities. Because the Sackler Defendants demanded much more detail, staff had to create special reports just for them.

73. ~~84.~~ Examples of the Sackler Defendants direct efforts and control over the Purdue Entities, and subsequently the Rhodes Entities included the following:

- Defendant Richard Sackler even went into the field to directly promote opioids to doctors and supervise representatives face to face.
- In connection with a single meeting in 2011, sales and marketing staff scrambled to prepare responses to questions from the Sackler Defendants, Defendant Mortimer Sackler asked about launching a generic version of OxyContin to capture more cost sensitive patients.
- Defendant Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert.
- Defendant Jonathan Sackler demanded reports on the changes in market share for opioids, focusing on dose strength, so as to increase sales and profits.

Russell Gasdia, Vice President of Sales and Marketing for the Purdue Entities, complained to the then CEO about the Sackler Defendants' invasive control and interference with sales activities: "Anything you can do to reduce the direct contact of Richard [Sackler] into the

organization is appreciated.”

- To convince the Sackler Defendants to make him CEO, Craig Landau wrote a plan that he entitled: “SACKLER PHARMA ENTERPRISE.” The plan began by recognizing that the Sackler Defendants in fact controlled the company just as though they were operating as chief executive officers. The Sackler Defendants ran “the global Sackler pharmaceutical enterprise ... with the Board of Directors serving as the ‘de-facto’ CEO.”

74. ~~85.~~ The Sackler Defendants concealed their complete control and overwhelming daily involvement in the operations—of the Purdue Entities and the Rhodes Entities—at all costs. As early as 2000, the Sackler Defendants were warned that a reporter was “sniffing about the OxyContin abuse story.” Concerned that their enterprise, and corresponding personal profiteering may be exposed, the Sackler Defendants put the threat on the agenda for the next Board meeting and began efforts to cover their activities—to cover their tracks. The Sackler Defendants outlined and executed an aggressive plan that “deflects attention away from the company owners.”

75. ~~86.~~ More recently, in November 2016, the Sackler Defendants instructed staff for the Purdue Entities and the Rhodes Entities to prepare press statements denying the Sackler Defendants’ involvement. The Sackler Defendants’ draft release stated—falsely—that the “Sackler family members hold no leadership roles in the companies owned by the family trust.”

~~87.~~ The Sackler Defendants sole focus was on increasing their personal wealth, regardless of the means—legal or illegal—and without regard to the impact on its patients and the public. As far back as 1999, when employee Michael Friedman reported that the Purdue Entities were making more than \$20,000,000 *per week*, Richard Sackler replied that the sales were “not so great.... if we are to do 900M this year, we should be running at 75M/month.”

76. ~~88.~~ From the massive profits collected by the Purdue Entities and the Rhodes Entities,

notably as a result of their wrongful conduct, the Sackler Defendants paid themselves billions of dollars. By way of example, for the period from 2007 until 2018, the Sackler Defendants repeatedly voted themselves payouts of profits in excess of \$4 billion—profits that were gleaned in part from their improper activities in the Commonwealth of Kentucky.

77. ~~89.~~ Notably, because of the Sackler Defendants' improper activities, the Purdue Entities were the subject of criminal and civil charges in 2007—stemming again from the blatant misrepresentations and deceptive marketing of OxyContin. The Sackler Defendants settled the charges and agreed to pay a \$635 million settlement—a record setting settlement. The Sackler Defendants did not change their wrongful conduct but instead treated the settlement as a price of doing business.

78. ~~90.~~ Also in 2007, the Sackler Defendants entered into a settlement for the Purdue Entities with twenty-seven (27) states for violating Consumer Protection Act protections—for its improper and systemically extensive off-label marketing of OxyContin, and for its failure to truthfully and adequately disclose the known risks of abuse and diversion. Again, the Sackler Defendants' behavior did not change.

79. ~~91.~~ Again in 2007, the Sackler Defendants created the Rhodes Entities as a separate entity from the Purdue Entities. The goal according to a former senior manager at the Purdue Entities was to create a “landing pad” for the Sackler Defendants—recognizing and preparing for the inevitable likelihood that the Purdue Entities would be engulfed by the OxyContin opioid crisis. The Rhodes Entities would provide a fresh start of sorts—but with the same illicit marketing, sale, and distribution of opioids.

~~92.~~ That the Sackler Defendants operated the Rhodes Entities using the same improper methods and under the same level of control and direction was exposed in a 2017

Financial Times article. The article revealed that the Rhodes Entities continued to use the same employee handbook and that employees reported that “little distinction is made internally between the two companies.” Together, Rhodes and Purdue accounted for 14.4 million opioid prescriptions in the United States in 2016.

80. ~~93.~~ Under the Sackler Defendants’ continuing dominating control, the Purdue Entities and the Rhodes Entities continued to mislead the public—to aggressively market the false perception that opioids were safe and effective for long-term use. As a direct result, and at the expense of the public including the Commonwealth of Kentucky, the Sackler Defendants continued to reap billions in illicit profits.

81. ~~94.~~ The Sackler Defendants’ improper actions were knowing, intentional, and with reckless disregard for their patients and the public—specifically, directed to the Commonwealth of Kentucky.

82. ~~95.~~ The Sackler Defendants’ misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

d. Abbott Entities.

83. ~~96.~~ Defendant, **Abbott Laboratories** (“Abbott Labs”), is an Illinois corporation with its principal place of business in Abbott Park, Illinois.

84. ~~97.~~ Defendant **Abbott Laboratories, Inc.** (“Abbott Inc”) is a subsidiary of Abbott Laboratories, whose principal place of business is also in Abbott Park, Illinois.

~~98.~~ Defendants Abbott Labs and Abbott Inc (collectively the “**Abbott Entities**”) acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

85. ~~99.~~ The Abbott Entities were primarily engaged in the promotion, marketing and distribution of opioids throughout the Commonwealth of Kentucky pursuant to a co-promotional agreement with the Purdue Entities.

86. ~~100.~~ Based on the Abbott Entities efforts, in conjunction with the Purdue Entities and Sackler Defendants, OxyContin became the largest selling opioid in the U.S. Pursuant to the co-promotional agreement, the Abbott Entities received twenty-five to thirty percent (25-30%) of all net sales for OxyContin prescriptions written by doctors its sales force called on.

87. ~~101.~~ With the Abbott Entities' marketing assistance—specifically, its sales force, sales of OxyContin dramatically increased from \$49 million in its first full year on the market to \$1.2 billion in 2002. Over the life of the co-promotional agreement, the Abbott Entities collected nearly \$500 million—a substantial portion of which resulted from sales throughout the Commonwealth of Kentucky. As with the Purdue Entities, the Rhodes Entities, and the Sackler Defendants, the Abbott Entities' significant profits were the product of blatant misrepresentations, improper off-label marketing, and disinformation.

88. ~~102.~~ The Abbott Entities' improper actions in their sale of OxyContin is well established. An October 28, 2016 article from Psychology Today entitled *America's Opioid Epidemic* stated:

Abbott and Purdue actively misled prescribers about the strength and safety of the painkiller [OxyContin]. To undermine the policy of requiring prior authorization, they offered lucrative rebates to middlemen such as Merck Medco [now Express Scripts] and other pharmacy benefits managers on condition that they eased availability of the drug and lowered co-pays.

~~103.~~ The Abbott Entities' misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both

necessary, warranted, and required.

e. Teva Entities.

89. ~~104.~~ Defendant **Teva Pharmaceutical Industries, Ltd.** (“Teva Ltd.”) is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Ltd. is traded on the New York Stock Exchange (NYSE: TEVA). In its most recent Form 10-K filed with the Securities and Exchange Commission, Teva Ltd. stated that it is the leading generic drug company in the United States. Teva Ltd. operates globally, with significant business transactions in the United States. In 2018, its gross profit from North American operations was \$4.979 million.

90. ~~105.~~ Defendant **Cephalon, Inc.** (“Cephalon”) is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva Ltd. acquired Cephalon in October 2011. Cephalon Inc. is a wholly owned and controlled subsidiary of Teva Ltd.

91. ~~106.~~ Defendant **Teva Pharmaceuticals USA, Inc.** (“Teva USA”) is a Delaware corporation with its principal place of business in North Wales, Pennsylvania, and is a wholly owned and controlled subsidiary of Teva Ltd.

92. ~~107.~~ Defendants Teva Pharmaceutical Industries, Ltd., Cephalon, Inc., and Teva Pharmaceuticals USA, Inc. (collectively the “**Teva Entities**”) acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

~~108.~~ Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora throughout the Commonwealth of Kentucky.⁴ Actiq has been approved by the FDA only for the “management of breakthrough cancer pain in patients 16 years and older with

⁴ Teva USA also sells generic opioids in the United States, including generic opioids previously sold by Allergan PLC, whose generics business Teva Ltd., Teva USA’s parent company based in Israel, acquired in August 2016. *See infra*.

malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain.” Fentora has been approved by the FDA only for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.” In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay a \$425 million penalty for its illegal actions.

93. ~~109.~~ All of Cephalon’s promotional websites, including those for Actiq and Fentora, display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon’s and Teva USA’s sales as its own, and its year-end report for 2012—the year immediately following the Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including *inter alia* sales of Fentora.

94. ~~110.~~ Through interrelated operations like these, Teva Ltd. actively operates in the United States—specifically the Commonwealth of Kentucky—through its directly controlled and managed subsidiaries Cephalon and Teva USA. As a result of these efforts, the United States is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies’ business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder.

~~111.~~ In furtherance of their opioid promotions, marketing, and resulting sales, the Teva Entities—through Cephalon—made thousands of payments to physicians nationwide, including in the Commonwealth of Kentucky, ostensibly for activities including participating on speakers’

bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, many of whom were not oncologists and did not treat cancer pain, but in fact to deceptively promote and maximize the use of opioids—to manipulate the market thereby increasing their corresponding sales and resulting profits.

95. ~~112.~~ The Teva Entities' misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

f. Allergan Entities.

96. ~~113.~~ Defendant **Allergan PLC** ("Allergan PLC") is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Shares of Allergan are traded on the New York Stock Exchange (NYSE: AGN). In its most recent Form 10-K filed with the SEC, Allergan PLC stated that it does business in the United states through its U.S. Specialized Therapeutics and U.S. General Medicine segments, which generated nearly 80% of the company's \$15.8 billion in net revenue during the year ended December 31, 2018.

97. ~~114.~~ Defendant **Actavis PLC** ("Actavis PLC") acquired Allergan in March 2015, and the combined company changed its name to Allergan PLC in March 2015.

98. ~~115.~~ Defendant **Watson Pharmaceuticals, Inc.** ("Watson Pharma") acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then to Actavis PLC in October 2013.

~~116.~~ Defendant **Watson Laboratories, Inc.** ("Watson Labs") is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Defendant Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc).

99. ~~117.~~ Defendant **Actavis Pharma, Inc.** (f/k/a Actavis, Inc.) ("Actavis Pharma") is a

Delaware corporation with its principal place of business in New Jersey and was *formerly* known as Watson Pharma, Inc.

100. ~~118.~~ Defendant **Actavis LLC** (“Actavis LLC”) is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

101. ~~119.~~ At all relevant times, Allergan PLC, Actavis PLC, Watson Pharma, Watson Labs, Actavis Pharma, and Actavis LLC (collectively, the “**Allergan Entities**”) acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

102. ~~120.~~ The Allergan Entities manufactured multiple branded and generic opioids, including Kadian, Duragesic, Opana, and Norco, which were in turn promoted, marketed, distributed, and sold throughout the Commonwealth of Kentucky.

103. ~~121.~~ The Allergan Entities are each owned, controlled and subject to the exclusive direction of Allergan PLC who in turn directly profited from these same promotional, marketing, and sales efforts.⁵

104. ~~122.~~ In furtherance of their opioid promotions, marketing, and resulting sales, the Allegan Entities—through Actavis—made thousands of payments to physicians nationwide, including in the Commonwealth of Kentucky, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids—to manipulate the market thereby increasing their corresponding sales and resulting profits.

~~123.~~ The Allergan Entities’ misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both

⁵ Actavis PLC was sold to Teva Ltd. in August 2016.

necessary, warranted, and required.

g. Endo Entities.

105. ~~124.~~ Defendant **Endo Health Solutions Inc.** (“Endo Health”) is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

106. ~~125.~~ Defendant **Endo Pharmaceuticals Inc.** (“Endo Pharma”) is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

107. ~~126.~~ Defendant **Endo International PLC** (“Endo PLC”) has global headquarters in Dublin, Ireland and U.S. headquarters in Malvern, Pennsylvania.

108. ~~127.~~ Defendant **Par Pharmaceutical, Inc.** (“Par Pharma”) is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharma is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.

109. ~~128.~~ Defendant **Par Pharmaceuticals Companies, Inc.** (“Par Inc.”) is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Inc. was acquired by Endo PLC in September 2015 and is an operating company of Endo PLC.

110. ~~129.~~ At all relevant times, Endo Health, Endo Pharma, Endo PLC, Par Pharma, and Par Inc. (collectively the “**Endo Entities**”) acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

~~130.~~ The Endo Entities manufactured multiple branded and generic opioids, including Opana/Opana ER, Percodan, Percocet, generic versions of oxycodone, oxymorphone, hydromorphone and hydrocodone, which were in turn promoted, marketed, distributed, and sold throughout the Commonwealth of Kentucky.

111. ~~131.~~ The sale of Opioids made up roughly \$403 million of the Endo Entities' gross

revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013 and accounted for 10% of total revenue in 2012. The Endo Entities also manufacture, promote, market and sell generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

112. ~~132.~~ In furtherance of its opioid promotions, marketing, and resulting sales, the Endo Entities made thousands of payments to physicians nationwide, including in the Commonwealth of Kentucky, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids—to manipulate the market thereby increasing their corresponding sales and resulting profits.

113. ~~133.~~ The Endo Entities' misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

h. Mallinckrodt Entities.

114. ~~134.~~ Defendant **Mallinckrodt PLC** ("Mallinckrodt PLC") is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt PLC was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien PLC, which was fully transferred to Mallinckrodt PLC in June of that same year. Mallinckrodt PLC operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri.

~~135.~~ Defendant **Mallinckrodt LLC** ("Mallinckrodt LLC") is a Delaware corporation and also maintains its U.S. headquarters in Hazelwood, Missouri.

115. ~~136.~~ Defendant **SpecGx LLC** (“SpecGx”) is a Delaware limited liability company with its U.S. headquarters in Clayton, Missouri. SpecGx is a wholly owned subsidiary of Mallinckrodt PLC.

116. ~~137.~~ At all relevant times, Mallinckrodt PLC, Mallinckrodt LLC, and SpecGx LLC (collectively, the “**Mallinckrodt Entities**”) acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

117. ~~138.~~ The Mallinckrodt Entities are the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescription sales.

118. ~~139.~~ The Mallinckrodt Entities manufactured branded opioids—Exalgo, Roxicodone, and Xartemis—which were in turn promoted, marketed, distributed, and sold throughout the Commonwealth of Kentucky. Mallinckrodt promoted its branded opioid products with its own direct sales force.

119. ~~140.~~ In addition to its branded opioids, the Mallinckrodt Entities has been a leading manufacturer of generic opioids. Among the generic opioids the Mallinckrodt Entities manufacture, or manufactured, are the following: morphine; fentanyl; oxycodone; hydrocodone; hydromorphone; naltrexone; oxymorphone; methadone; buprenorphine; and naloxone.

~~141.~~ The Mallinckrodt Entities estimated that in 2015 it received approximately 25% of the U.S. Drug Enforcement Administration’s (“DEA”) entire annual quota for allowable manufacture of controlled substances. The Mallinckrodt Entities also estimated, based on IMS Health data for the same period, that their generic opioids commanded approximately 23% market share of Schedules II and III opioid and oral solid dose medication sales in the U.S.

120. ~~142.~~ The Mallinckrodt Entities operate a vertically integrated business in the United

States: (i) importing raw opioid materials, (ii) manufacturing generic opioid products, and (iii) promoting, marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

121. ~~143.~~ In furtherance of its opioid promotions, marketing, and resulting sales, the Mallinckrodt Entities made thousands of payments to physicians nationwide, including in the Commonwealth of Kentucky, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids—to manipulate the market thereby increasing their corresponding sales and resulting profits.

122. ~~144.~~ The Mallinckrodt Entities' misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

i. Johnson & Johnson Entities.

123. ~~145.~~ Defendant **Johnson & Johnson** ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

124. ~~146.~~ Defendant **Janssen Pharmaceuticals, Inc.** ("Janssen Pharma") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J. Janssen Pharma was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

~~147.~~ Defendant **Noramco, Inc.** ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. Noramco, Inc. was an integral part of J&J's opium processing—the active pharmaceutical ingredients

(“APIs”) necessary for opioid pain medication.

125. ~~148.~~ At all relevant times, J&J, Janssen Pharma, and Noramco (collectively, the “**Johnson & Johnson Entities**”) acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

126. ~~149.~~ The Johnson & Johnson Entities manufactured branded opioids—including, Duragesic (Fentanyl), Nucynta (Tapentadol), Nucynta ER, Ultram (Tramadol), Ultram ER, Ultracet, and Tylox— which were in turn promoted, marketed and sold throughout the Commonwealth of Kentucky.

127. ~~150.~~ Before 2009, Duragesic accounted for at least \$1 billion in the Johnson & Johnson Entities annual sales. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

128. ~~151.~~ In furtherance of its opioid promotions, marketing, and resulting sales, the Johnson & Johnson Entities made thousands of payments to physicians nationwide, including in the Commonwealth of Kentucky, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids—to manipulate the market thereby increasing their corresponding sales and resulting profits.

~~152.~~ Further, as part of its “pain management franchise,” from the 1990s through at least 2016, the Johnson & Johnson Entities supplied—sold for a profit to—other opioid manufacturers with opioid API’s necessary to manufacture opioid drugs. Using a subsidiary based in Tasmania—Tasmanian Alkaloids Limited (“Tasmanian Alkaloids”), the Johnson & Johnson Entities cultivated and processed opium poppy plants to manufacture narcotic raw materials that were imported into the U.S. to be processed and made into the API’s necessary to

manufacture opioid drugs s necessary to manufacture opioid drugs.

129. ~~153.~~ The Tasmanian Alkaloids were imported and processed by the Johnson & Johnson Entities—using Defendant Noramco—and subsequently sold to other opioid manufacturers in the U.S. As a result, the Tasmanian Alkaloids were a crucial and key component of the Johnson & Johnson Entities’ “pain management franchise” in the U.S. This franchise also encompassed all of the Johnson & Johnson Entities’ opioid products.

130. ~~154.~~ Specifically, the Johnson & Johnson Entities supplied the following opioid API’s to other opioid drug manufacturers in the U.S., including Purdue and Teva: oxycodone, hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone.

131. ~~155.~~ The Johnson & Johnson Entities’ efforts resulted in their “pain management franchise” becoming the number one (#1) supplier of narcotic API’s in the U.S. By effectively cornering the market with its API production—using opium poppy plant production, extraction, and importation—the Johnson & Johnson Entities were uniquely positioned to provide U.S. opioid manufacturers with what it deemed “Security of Supply” and “Direct Access to Narcotic Raw Material - From Our Fields to Your Formulations.” Using its franchise, the Johnson & Johnson Entities supplied the necessary opioid component—oxycodone API—to U.S. opioid manufacturers.

132. ~~156.~~ To increase demand, market share, and ultimately their profits, the Johnson & Johnson Entities began a project to develop a *high* thebaine⁶ poppy—subsequently named the

Norman Poppy. The Johnson & Johnson Entities described the *Norman Poppy* as a *transformational* technology that would drive the significant growth of the oxycodone market.

⁶ Thebaine, also known as codeine methyl enol ether, is an opiate alkaloid.

133. ~~157.~~ The Johnson & Johnson Entities’ misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

j. Amneal Entities.

134. ~~158.~~ Defendant **Amneal Pharmaceuticals, LLC** (“Amneal LLC”) is a Delaware limited liability company with its principal place of business in New Jersey.

135. ~~159.~~ Defendant **Amneal Pharmaceuticals, Inc.** (“Amneal Inc.”) is a Delaware corporation with its principal place of business in New Jersey. Amneal Inc. is the managing member of Amneal LLC and conducts and exercises full control over all activities of Amneal LLC.

136. ~~160.~~ At all relevant times, Amneal LLC and Amneal Inc. (collectively, the “Amneal Entities”) acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

137. ~~161.~~ The Amneal Entities manufactured multiple generic opioids, including versions of Percocet, Ultracet, Ultram, Suboxone, Vicoprofen, and Narco, which were in turn promoted, marketed, distributed and sold throughout the Commonwealth of Kentucky.

138. ~~162.~~ The Amneal Entities’ misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

k. Mylan.

~~163.~~ Defendant **Mylan Pharmaceuticals, Inc.** (“Mylan”) is a Pennsylvania corporation with its principal place of business in Canonsburg, Pennsylvania.

139. ~~164.~~ Mylan manufactured opioids—including many Schedule II controlled substances

such as Fentanyl—which were in turn promoted, marketed, distributed, and sold throughout the Commonwealth of Kentucky.

140. ~~165.~~ Mylan’s misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

l. West-Ward.

141. ~~166.~~ Defendant **West-Ward Pharmaceuticals Corp.**, k/n/a Hikma Pharmaceuticals, PLC (“West-Ward”) is a multinational pharmaceutical company with its headquarters in London, United Kingdom, and its principal place of business in the United States located in Eastontown, New Jersey.

142. ~~167.~~ West-Ward manufactured opioids—which were in turn promoted, marketed, distributed, and sold throughout the Commonwealth of Kentucky.

143. ~~168.~~ West-Ward’s misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

m. KVK-Tech.

144. ~~169.~~ Defendant KVK Tech, Inc. (“KVK”) is a Pennsylvania business entity with its principal place of business in Pennsylvania.

145. ~~170.~~ KVK-Tech manufactured opioids— which were in turn promoted, marketed, distributed, and sold throughout the Commonwealth of Kentucky.

~~171.~~ KVK-Tech’s misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

n. Assertio Entities.

146. ~~172.~~ Defendant **Assertio Therapeutics, Inc.** f/k/a Depomed, Inc.

(“Assertio”) is a Delaware corporation with its principal place of business in Lake Forest, Illinois.

147. ~~173.~~ Defendant **Depomed Inc.** (“Depomed”) is a California corporation with its principal place of business in Newark, California.

148. ~~174.~~ At all relevant times, Assertio and Depomed (collectively, the “**Assertio Entities**”) acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

149. ~~175.~~ The Assertio Entities market themselves as a specialty pharmaceutical company focused on pain and other central nervous system conditions. In this capacity, in April 2015, the Assertio Entities acquired the rights to Nucynta and Nucynta ER for \$1.05 billion from the Johnson & Johnson Entities. Prior to and subsequent to the acquisition, the Assertio Entities manufactured opioids which were in turn promoted, marketed, distributed, and sold throughout the Commonwealth of Kentucky.

150. ~~176.~~ The Assertion Entities’ misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

2. Wholesale Distributor Defendants.

~~177.~~ The Wholesale Distributor Defendants are defined below. At all relevant times, the Wholesale Distributor Defendants have promoted, marketed, distributed, and sold opioids throughout the Commonwealth of Kentucky—activities which have universally failed to comply with their legal obligations to their patients and to the public at large.

151. ~~178.~~ The Wholesale Distributor Defendants were, and remain, engaged in “wholesale

distribution” as defined by Kentucky law. The Wholesale Distributor Defendants were, and remain, a substantial cause for the volume of prescription opioids plaguing the Commonwealth of Kentucky.

152. ~~179.~~ Collectively, Amerisource Bergen Entities, Anda, Cardinal Health, CVS, Kroger, McKesson, Rite Aid Corp, Smith Drug, Walgreens, and Walmart are referred to herein as the “**Wholesale Distributor Defendants.**” *See infra.*

a. AmerisourceBergen Entities

153. ~~180.~~ Defendant **AmerisourceBergen Drug Corporation** (“AmerisourceBergen”) is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania.

154. ~~181.~~ Defendant **H. D. Smith, LLC** f/k/a H. D. Smith Wholesale Drug Co. (“H. D. Smith”) is a wholesaler of pharmaceutical drugs that distributed opioids throughout the Commonwealth of Kentucky. H. D. Smith was a privately held independent pharmaceuticals distributor of wholesale brand, generic and specialty pharmaceuticals and is a Delaware corporation with its principal place of business in Illinois. H. D. Smith Wholesale Drug Co. was restructured and is currently doing business as H. D. Smith, LLC.

155. ~~182.~~ H.D. Smith LLC’s sole member is H. D. Smith Holdings, LLC, and its sole member is H. D. Smith Holding Company, a Delaware corporation with its principal place of business in Illinois. H. D. Smith is the largest independent wholesaler in the United States. In January 2018, Defendant AmerisourceBergen acquired H. D. Smith.

~~183.~~ At all relevant times, AmerisourceBergen and H. D. Smith (collectively, the “**AmerisourceBergen Entities**”) acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

156. ~~184.~~ The AmerisourceBergen Entities are wholesale distributors of opioids throughout

the Commonwealth of Kentucky.

157. ~~185.~~ The AmerisourceBergen Entities' misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

b. Anda.

158. ~~186.~~ Defendant **Anda, Inc.**, ("Anda") is a Florida corporation with its principal place of business in Weston, Florida.

159. ~~187.~~ Anda through its various subsidiaries and affiliated entities, including Anda Pharmaceuticals, Inc., is the fourth largest wholesale distributor of generic pharmaceuticals in the United States. In October 2016, the Teva Entities acquired Anda from the Allegan Entities for \$500 million in cash.

160. ~~188.~~ Anda has, at all relevant times, acted as a wholesale distributor of opioids throughout the Commonwealth of Kentucky.

161. ~~189.~~ Anda's misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

c. Cardinal Health.

162. ~~190.~~ Defendant **Cardinal Health, Inc.** ("Cardinal Health") is an Ohio Corporation with its principal place of business in Dublin, Ohio.

~~191.~~ Cardinal Health is a global distributor of pharmaceutical drugs and medical products. It is one of the largest wholesale distributors of opioids in the United States with annual revenues in excess of \$121.5 billion. Additionally, in December 2013, Cardinal Health formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing

operation in the United States.

163. ~~192.~~ Cardinal Health has, at all relevant times, acted as a wholesale distributor of opioids throughout the Commonwealth of Kentucky.

164. ~~193.~~ Cardinal Health's misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

d. CVS.

165. ~~194.~~ Defendant **CVS Health Corporation LLC** ("CVS") is a Delaware limited liability company with its principal place of business in Rhode Island.

166. ~~195.~~ CVS has, at all relevant times, acted as a wholesale distributor of opioids throughout the Commonwealth of Kentucky.

167. ~~196.~~ CVS' misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

e. Kroger.

168. ~~197.~~ Defendant **Kroger Company** ("Kroger") is an Ohio corporation with headquarters in Cincinnati, OH.

169. ~~198.~~ Kroger conducts business as a pharmaceutical wholesale distributor under the following named business entities, each of which is wholly-owned and controlled by Kroger: Kroger Limited Partnership I and Kroger Limited Partnership II (collectively "Kroger").

~~199.~~ Kroger has, at all relevant times, acted as a wholesale distributor of opioids throughout the Commonwealth of Kentucky.

170. ~~200.~~ Kroger's misconduct and illegal actions, as further addressed herein, have caused

injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

f. McKesson.

171. ~~201.~~ Defendant **McKesson Corporation** (“McKesson”) dba McKesson Drug Company is a Delaware corporation with its principal place of business located in Irving, Texas.

172. ~~202.~~ McKesson is the largest pharmaceutical distributor in North America. McKesson delivers approximately one-third of all pharmaceuticals used in North America. For fiscal year ending on March 31, 2018, McKesson generated revenues of \$208 billion, placing it seventh on the Fortune 500 list. In its 2018 Annual Report, McKesson stated that it “partner[s] with [pharmaceutical] manufacturers, providers, pharmacies, governments and other organizations in healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively.”

173. ~~203.~~ According to its 2017 Annual Report, McKesson’s “pharmaceutical distribution business operates and serves customer locations in all 50 states and Puerto Rico through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities.”

~~204.~~ In January 2017, McKesson paid a record \$150 million to resolve an investigation by the U.S. Department of Justice (“DOJ”) for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan, and Colorado. The DOJ described these “staged suspensions” as “among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor.”

174. ~~205.~~ McKesson has, at all relevant times, acted as a wholesale distributor of opioids

throughout the Commonwealth of Kentucky.

175. ~~206.~~ McKesson's misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

g. Rite Aid Corp.

176. ~~207.~~ Defendant **Rite Aid Corporation** ("Rite Aid") is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania.

177. ~~208.~~ Rite Aid has, at all relevant times, acted as a wholesale distributor of opioids throughout the Commonwealth of Kentucky.

178. ~~209.~~ Rite Aid's misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

h. Smith Drug.

179. ~~210.~~ Defendant **Smith Drug Company, Inc.** ("Smith Drug") is a Kentucky corporation with its principal office located in Hodgenville, Kentucky.

180. ~~211.~~ Smith Drug, at all relevant times, acted as a wholesale distributor of opioids throughout the Commonwealth of Kentucky.

181. ~~212.~~ Smith Drug's misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

i. Walgreens.

~~213.~~ Defendant **Walgreen Co.** ("Walgreens") is an Illinois corporation with its principal place of business in Deerfield, Illinois.

182. ~~214.~~ Walgreens has, at all relevant times, acted as a wholesale distributor of opioids throughout the Commonwealth of Kentucky.

183. ~~215.~~ Walgreens' misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

j. Walmart.

184. ~~216.~~ Defendant **Walmart Inc.** ("Walmart") f/k/a Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

185. ~~217.~~ Walmart has, at all relevant times, acted as a wholesale distributor of opioids throughout the Commonwealth of Kentucky.

186. ~~218.~~ Walmart's misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

3. Retail Pharmacy Defendants.

187. ~~219.~~ As the title implies, the Retail Pharmacy Defendants operate as retail pharmacies in the Commonwealth of Kentucky. In that capacity, the Retail Pharmacy Defendants sold, transferred, dispensed, and distributed opioids—notably without fulfilling their common law and statutory duties to their patients and to the public.

188. ~~220.~~ The Retail Pharmacy Defendants, for their own financial gain and without regard to the resulting damages caused, willfully and knowingly participated in the distribution of opioids throughout the Commonwealth of Kentucky.

~~221.~~ Collectively, CVS Pharmacy, Fred's Stores, Kroger, Rite Aid KY, Walgreens, and Walmart are referred to herein as the "**Retail Pharmacy Defendants.**" *See infra.*

a. CVS Pharmacy.

189. ~~222.~~ Defendant **Kentucky CVS Pharmacy LLC** (“CVS Pharmacy”) is a Kentucky limited liability company with a principal office in Woonsocket, Rhode Island.

190. ~~223.~~ CVS Pharmacy operated and conducted business as a retail pharmacy—selling, transferring, dispensing, and distributing opioids, throughout the Commonwealth of Kentucky.

191. ~~224.~~ CVS Pharmacy’s misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

b. Fred’s Stores.

192. ~~225.~~ Defendant **Fred’s Stores of Tennessee, Inc.** (“Fred’s Pharmacy”) is a Delaware corporation with a principal office in Dallas, Texas.

193. ~~226.~~ Fred’s Stores operated and conducted business as a retail pharmacy—selling, transferring, dispensing, and distributing opioids, throughout the Commonwealth of Kentucky.

194. ~~227.~~ Fred’s Store’s misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

c. Kroger.

195. ~~228.~~ Defendant **Kroger Company** (“Kroger”) is an Ohio corporation with headquarters in Cincinnati, OH.

196. ~~229.~~ Kroger operated and conducted business as a retail pharmacy—selling, transferring, dispensing, and distributing opioids, throughout the Commonwealth of Kentucky.

230. Kroger's misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary,

warranted, and required.

d. Rite Aid KY.

197. ~~231.~~ Defendant **Rite Aid of Kentucky, Inc.** (“Rite Aid KY”) is a Kentucky corporation with a principal office in Harrisburg, Pennsylvania.

198. ~~232.~~ Rite Aid KY operated and conducted business as a retail pharmacy—selling, transferring, dispensing, and distributing opioids, throughout the Commonwealth of Kentucky.

199. ~~233.~~ Rite Aid KY’s misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

e. Walgreens.

200. ~~234.~~ Defendant **Walgreen Co.** (“Walgreens”) dba Walgreens is an Illinois corporation with its principal place of business in Deerfield, Illinois.

201. ~~235.~~ Walgreens operated and conducted business as a retail pharmacy—selling, transferring, dispensing, and distributing opioids, throughout the Commonwealth of Kentucky.

202. ~~236.~~ Walgreens’ misconduct and illegal actions, as further addressed herein, have caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

f. Walmart.

203. ~~237.~~ Defendant **Walmart Inc.** (“Walmart”) f/k/a Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

~~238.~~ Walmart operated and conducted business as a retail pharmacy—selling, transferring, dispensing, and distributing opioids, throughout the Commonwealth of Kentucky.

204. ~~239.~~ Walmart’s misconduct and illegal actions, as further addressed herein, have

caused injuries to and throughout the Commonwealth of Kentucky for which relief is both necessary, warranted, and required.

C. State Government Defendants.

205. ~~240.~~ Defendant **Commonwealth of Kentucky** (“Kentucky”) is a sovereign state and governmental entity.

206. ~~241.~~ Defendant **Matthew Bevin** (“Governor Bevin”) is the Governor of the Commonwealth of Kentucky. The Governor is the state’s chief executive officer including, inter alia, overseeing and appointing the members of the Kentucky Pharmacy Board.

207. ~~242.~~ Defendant **Kentucky Pharmacy Board** (the “Pharmacy Board”) is a state entity, entrusted with administering and regulating the manufacture, distribution, marketing, sale, and dispensing of opioids throughout the Commonwealth of Kentucky.

208. ~~243.~~ Defendant **Cabinet for Health and Family Services** (the “Cabinet”) is a state entity, entrusted with administering and regulating the manufacture, distribution, marketing, sale, and dispensing of controlled substances throughout the Commonwealth of Kentucky.

209. ~~244.~~ Collectively, Kentucky, Governor Bevin, the Cabinet, and the Pharmacy Board, are referred to herein as the **State Government Defendants.**” The State Government Defendants are sued in their official capacities.

FACTUAL BACKGROUND

A. The Opioid Epidemic.

1. The National Opioid Epidemic.

~~245.~~ The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States. Prescription opioids have become widely prescribed for chronic pain—not just acute pain.

241. ~~246.~~ By 2010, enough prescription opioids were sold to medicate every adult in the

United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.

242. ~~247.~~ By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses were at epidemic levels. The news release noted:

- ☐ The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
- ☐ More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
- ☐ Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
- ☐ The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people - reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.
- ☐ Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.
- ☐ Almost 5,500 people start to misuse prescription painkillers every day.

~~248.~~ The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population. Many Americans have become addicted to prescription opioids, and the number of deaths due to prescription opioid overdose has escalated. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.

243. ~~249.~~ In its most recent 2017 Overdose Fatality Report, the Kentucky Office of Drug Control Policy found that:

Substance abuse, particularly the diversion and abuse of prescription drugs along with heroin and illicit fentanyl, remains one of the most critical public health and safety issues facing Kentucky. Over the past decade, the number of Kentuckians who die from drug overdoses has steadily climbed to more than 1,500 this year, exacting a devastating toll on families, communities, social services and economic growth.

244. ~~250.~~ The same report noted that the number of opioid related deaths continued to increase throughout the Commonwealth of Kentucky.

Kentucky overdose fatalities increased in 2017. Overdose deaths of Kentucky residents, regardless of where the death occurred, and non-residents who died in Kentucky, totaled 1,565 as reported to the Office of Vital Statistics in June 2018. Of those, 1,468 were Kentucky residents. That's compared to 1,404 overdose deaths counted in the 2016 report. Within the 1,565 overdose deaths, toxicology was available for 1,468 of those. A review of cases autopsied by the Kentucky Medical Examiner's Office and toxicology reports submitted by coroners indicates that in 2017:

- ☐ People ages 35 to 44 were the largest demographic in overdose deaths. Followed by 45 to 54.

* * * * *

- ☐ Fentanyl was involved in 763 Kentucky resident overdose deaths. That accounts for 52 percent of all deaths, up from 47 percent in 2016.

~~251.~~ Oxycodone addiction has been a source of opioid addiction in America since the 1960s, with a spike in popularity in the mid-1990s. Throughout this time, the U.S. government and researchers studied oxycodone addiction and misuse. Their research revealed shocking statistics, including:

- ☐ Oxycodone products sell for an average price of \$1 per milligram on the streets;

- ☐ In 1996, before OxyContin came out, the federal government recorded 49 oxycodone-related deaths. In 1999, the federal government recorded 262 oxycodone-related deaths
- ☐ In 2013, 2 percent of eighth graders, 3.4 percent of 10th graders and 3.6 percent of 12th graders surveyed in the Monitoring The Future study said that they abused OxyContin in the previous year.
- ☐ Of the 20.5 million Americans with addiction in 2015, 2 million were addicted to prescription narcotics including oxycodone.
- ☐ Opioid addiction and abuse led to 20,101 overdose deaths in 2015.
- ☐ Women were at higher risk of prescription opioid abuse and addiction than men.
- ☐ 4 out of 5 (80%) new heroin users started out misusing prescription painkillers.

245. ~~252.~~ The CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty (40) times more likely to be addicted to heroin.

246. ~~253.~~ Heroin is pharmacologically similar to prescription opioids. Just as with opioids—e.g. OxyContin—heroin is made from the resin of poppy plants. Milky, sap-like opium is first removed from the pod of the poppy flower. This opium is then refined to make morphine, then further refined into different forms of heroin.

247. ~~254.~~ The majority of current heroin users report having used prescription opioids non- medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.

~~255.~~ The CDC reports that drug overdose deaths involving heroin continue to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large

increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use, specifically among persons who report past-year dependence or abuse. The increased availability of heroin combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.

248. ~~256.~~ The societal costs of prescription drug abuse are significant. Across the nation, local governments struggle with the ever-expanding epidemic of opioid addiction and abuse. Every day, more than 90 Americans lose their lives after overdosing on opioids.

249. ~~257.~~ The National Institute on Drug Abuse identifies misuse and addiction to opioids as “a serious national crisis that affects public health as well as social and economic welfare.” The economic burden of prescription opioid misuse alone is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.

250. ~~258.~~ The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.

~~259.~~ The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country. Meanwhile, the Manufacturer (“Marketing”) Defendants, the Wholesale Distributor Defendants, and Retail Pharmacy Defendants extract billions of dollars of revenue from the addicted American public while public entities such as the

Plaintiffs incur significant economic damages caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

251. ~~260.~~ The Manufacturer (“Marketing”) Defendants and the Wholesale Distributor Defendants have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or contributing to the national, state, and local opioid epidemic.

2. Kentucky’s Opioid Epidemic.

252. ~~261.~~ The Commonwealth of Kentucky has been especially damaged by the national opioid crisis, with an opioid prescription rate of 128.4 per 100 persons, which ranks fourth in the country (U.S. median rate: 82.5) and a benzodiazepine prescription rate of 57.4 per 100 persons which ranks fifth nationally (U.S. median rate: 37.6).

253. ~~262.~~ As reported by the CDC, Kentucky’s drug overdose rate has increased more rapidly and has remained significantly higher than the national average. As already noted, according to the Kentucky Office of Drug Control Policy, fatal overdoses in Kentucky soared to unprecedented levels in 2016, jumping 7.4 percent to 1,404 overdose deaths. In 2015, Kentucky overdose deaths rose by 21.1 percent over the number overdose deaths in 2014. In 2016, three in ten Kentuckians (27%) said they knew someone with problems from prescription painkillers.

~~263.~~ According to data kept by KVC Kentucky, a behavioral health and child welfare organization in Lexington, the number of children in foster care in Kentucky rose from 6,000 in 2012 to 8,000 in 2015, with about a third of them entering the system because of their parents’ substance abuse. Children with parents addicted to drugs tend to stay in foster care longer, and they often enter the system having experienced significant trauma, which makes their care more expensive.

254. ~~264.~~ In Kentucky, data from hospital discharge records indicate the number of newborns with Neonatal Abstinence Syndrome, a collection of symptoms newborn babies experience in withdrawing from opioid medications taken by the mother, has increased 23-fold in the last decade.

255. ~~265.~~ While overall inpatient admissions for substance abuse treatment in Kentucky in 2015 (19,005) were down from 2005 (22,705), heroin and other opioids accounted for nearly half (46.2 percent) of those admissions in 2015, compared to just 11.6 percent in 2005.

256. ~~266.~~ Data maintained by the Agency for Healthcare Research and Quality for 2007 through 2016 document a sharp increase in opioid-related inpatient hospital stays in Kentucky. The annual rate of such stays per 100,000 population has continued to increase. Further, the rate of opioid related Emergency Department visits increased 65.6% in Kentucky between 2009 and 2014.

B. The Manufacturer (“Marketing”) Defendants’ False, Deceptive, and Illicit Marketing of Opioids.

257. ~~267.~~ The opioid epidemic did not happen by accident, but rather is the direct result of the conscious and calculated decision by the Manufacturer (“Marketing”) Defendants to significantly and exponentially increase their sales and resulting profits—without regard to the resulting damages to the end-user, the public, and ultimately the Plaintiffs.

258. ~~268.~~ Before the 1990s, generally accepted standards of medical practice dictated that opioids were for the treatment of acute short-term pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care.

~~269.~~ Due to the lack of evidence that opioids improved the ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time, and the serious risk of addiction and other negative side effects, the use of

opioids for chronic pain was discouraged and/or prohibited. As a result, the medical community generally did not prescribe opioids for chronic pain.

259. ~~270.~~ Each of the Manufacturer (“Marketing”) Defendants conducted, and has continued to conduct, a marketing scheme designed to persuade prescribers, end-users, and the public that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids.

260. ~~271.~~ In connection with this scheme, each of the Manufacturer (“Marketing”) Defendants spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

261. ~~272.~~ The Manufacturer (“Marketing”) Defendants have made false and misleading claims, contrary to the language on their drugs’ labels, regarding the risks of using their drugs that:

- ☐ downplayed the serious risk of addiction;
- ☐ created and promoted the concept of “pseudo-addiction” when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids;
- ☐ exaggerated the effectiveness of screening tools to prevent addiction;
- ☐ claimed that opioid dependence and withdrawal are easily managed;
- ☐ denied the risks of higher opioid dosages; and
- ☐ exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse and addiction.

~~273.~~ The Manufacturer (“Marketing”) Defendants falsely touted the benefits of long- term opioid use, including the unproven ability of opioids to improve function and quality of life,

even though there was no scientifically reliable evidence to support their marketing claims.

262. ~~274.~~ The Manufacturer (“Marketing”) Defendants have disseminated these common— and deceptive—messages to reverse the popular and medically accepted understanding of opioids and risks of ongoing opioid use. They disseminated these deceptive messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer (“Marketing”) Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded front groups.

263. ~~275.~~ The Manufacturer (“Marketing”) Defendants’ efforts were highly successful. Opioids are now the *most prescribed* class of drugs. Globally, opioid sales generated \$11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded \$8 billion in revenue annually since 2009.

264. ~~276.~~ In an open letter to the nation’s physicians in August 2016, the U.S. Surgeon General expressly connected this “urgent health crisis” to “heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.”

265. ~~277.~~ The resulting epidemic has resulted in an enormous oversupply (i.e. flood) of prescription opioids available for sale (the supply) and resulting illicit use, and a population of physically and psychologically dependent end-users (the demand). And when those end-users can no longer afford or obtain opioids from licensed dispensaries, they often turn to the illicit purchase of the supply or, faced with their addiction, turn to non-prescription opioids, including heroin.

~~278.~~ The Manufacturer (“Marketing”) Defendants knowingly intentionally, recklessly and with wholesale indifference to the negative impact continued their conduct, as alleged

herein, created the opioid nuisance and causing the harms and damages alleged herein.

1. The Manufacturer (“Marketing”) Defendants Used Multiple Avenues to Disseminate Their False and Deceptive Statements about Opioids.

266. ~~279.~~ The Manufacturer (“Marketing”) Defendants spread their false and deceptive statements by marketing their respective branded opioids directly to prescribers and end-users throughout the Commonwealth of Kentucky.

267. ~~280.~~ The deception included the use of seemingly unbiased and independent third parties controlled and manipulated by the Manufacturer (“Marketing”) Defendants to spread their false and deceptive statements trivializing and minimizing the risks and instead exhorting the benefits of opioids for the treatment of chronic pain.

268. ~~281.~~ The Manufacturer (“Marketing”) Defendants employed the same marketing plans and strategies and deployed the same messages throughout the Commonwealth of Kentucky.

269. ~~282.~~ Across the pharmaceutical industry, “core message” development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that the Manufacturer (“Marketing”) Defendants’ messages are coordinated for consistent delivery across their marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. Manufacturer (“Marketing”) Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

~~283.~~ Manufacturer (“Marketing”) Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising.

270. ~~284.~~ Manufacturer (“Marketing”) Defendants’ sales representatives and physician

speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

a. Direct Marketing.

271. ~~285.~~ The Manufacturer (“Marketing”) Defendants’ direct marketing of opioids generally proceeded on two tracks. First, each Manufacturer (“Marketing”) Defendant conducted and continues to conduct advertising campaigns exhorting the purported benefits of their branded drugs, while diminishing the significant risks. For example, upon information and belief, the Manufacturer (“Marketing”) Defendants spent more than \$14 million on medical journal advertising of opioids in 2011 – a three-fold increase from 2001.

272. ~~286.~~ Many of the Manufacturer (“Marketing”) Defendants’ branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, the Endo Entities distributed and made available on its website *opana.com* a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like a construction worker, a chef, and a teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

273. ~~287.~~ Upon information and belief, the Purdue Entities under the direction of the Sackler Defendants also ran a series of ads, called “Pain vignettes,” for OxyContin in 2012 in medical journals. These ads featured individuals with chronic pain and recommended OxyContin for each. One ad described a “54-year-old writer with osteoarthritis of the hands” and implied that OxyContin would help the writer work more effectively.

~~288.~~ Second, each Manufacturer (“Marketing”) Defendant promoted the use of opioids for chronic pain through “detailers”—sales representatives who visited individual doctors and

medical staff in their offices—and small-group speaker programs.

274. ~~289.~~ The Manufacturer (“Marketing”) Defendants have not corrected this coordinated campaign of misinformation. Instead, each Manufacturer (“Marketing”) Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, the Manufacturer (“Marketing”) Defendants spent in excess of \$168 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

275. ~~290.~~ The Manufacturer (“Marketing”) Defendants’ detailing to doctors was, and remains, highly effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence.

276. ~~291.~~ Even without such studies, the Manufacturer (“Marketing”) Defendants purchase, manipulate and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, the Manufacturer (“Marketing”) Defendants know their detailing to doctors is highly effective at enforcing their deceptive messages—resulting in continued significant sales and corresponding profits.

277. ~~292.~~ The Manufacturer (“Marketing”) Defendants’ detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis—one of the Allergan Entities—had been distributing promotional materials that “minimize[] the risks associated with Kadian and misleadingly suggest[] that Kadian is safer than has been demonstrated.” Those materials in particular “fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed.”

b. Indirect Marketing.

278. ~~293.~~ The Manufacturer (“Marketing”) Defendants’ also surreptitiously marketed their opioids using unbranded advertising, paid speakers and “key opinion leaders” (“KOLs”), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as “Front Groups”).

279. ~~294.~~ The Manufacturer (“Marketing”) Defendants deceptively marketed opioids throughout the Commonwealth of Kentucky through unbranded advertising—e.g., advertising that promotes opioid use generally but does not name a specific opioid.

280. ~~295.~~ This advertising was ostensibly created and disseminated by independent third parties, but by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer (“Marketing”) Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain.

281. ~~296.~~ Just as they controlled the distribution of their “core messages” via their own detailers and speaker programs, the Manufacturer (“Marketing”) Defendants controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education (“CME”) programs, and medical conferences and seminars. To this end, the Manufacturer (“Marketing”) Defendants used third-party public relations firms to help control those messages when they originated from third parties.

282. ~~297.~~ The Manufacturer (“Marketing”) Defendants marketed through third party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to, and typically is not reviewed, by the FDA or state regulators—e.g. Kentucky.

283. ~~298.~~ The Manufacturer (“Marketing”) Defendants also used third party, unbranded

advertising to give the false appearance that the deceptive messages came from an independent and objective source. Similar to the use of third party marketing by Big Tobacco, the Manufacturer (“Marketing”) Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive prescribers, end-users, and the public about the risks of opioid use for chronic pain.

284. ~~299.~~ The Manufacturer (“Marketing”) Defendants also solicited and retained doctors to serve, for payment, on their speakers’ bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided:

- ☐ incentives for doctors to prescribe specific opioids (so they might be selected to promote the drug);
- ☐ recognition and compensation for the doctors selected as speakers; and
- ☐ an opportunity to promote the drug through the speaker to his or her peers.

285. ~~300.~~ The speakers were then presented to the public under the false pretense that they were providing unbiased and medically accurate presentations when they were, in fact, presenting a script prepared by the Manufacturer (“Marketing”) Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct prior misrepresentations about the significant risks of opioids – including their use for management of chronic pain.

286. ~~301.~~ Similar to the collaborative marketing employed by Big Tobacco, the Manufacturer (“Marketing”) Defendants coordinated and controlled their deceptive marketing through third parties they controlled by:

- ☐ funding, assisting, encouraging, and directing doctors who served as KOLS; and
- ☐ funding, assisting, directing, and encouraging seemingly neutral and

credible Front Groups.

287. ~~302.~~ The Manufacturer (“Marketing”) Defendants then worked together with those KOLs and Front Groups to taint the sources that prescribers, end-users, and the public relied on for ostensibly “neutral” guidance, such as treatment guidelines, CME programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Manufacturer (“Marketing”) Defendants persuaded prescribers, end-users, and the public that what they have long known—that opioids are addictive drugs and unsafe in most circumstances for long-term use—was untrue, and that the compassionate treatment of pain required opioids.

288. ~~303.~~ In 2007, multiple States sued the Purdue Entities for engaging in unfair and deceptive practices in its marketing, promotion, and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited the Purdue Entities from making misrepresentations in the promotion and marketing of OxyContin in the future.

289. ~~304.~~ By using indirect marketing strategies, however, the Purdue Entities intentionally circumvented these restrictions. Such actions include contributing to the creation of misleading publications and prescribing guidelines which lack reliable scientific basis and promote prescribing practices which have worsened the opioid crisis.

290. ~~305.~~ Pro-opioid doctors are one of the most important avenues that the Manufacturer (“Marketing”) Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use.

291. ~~306.~~ The Manufacturer (“Marketing”) Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York

settlement with the Purdue Entities that their website “In the Face of Pain” failed to disclose that doctors who provided testimonials on the site were paid by the Purdue Entities and concluded that this failure to disclose evidence of these financial conflicts of interest and tainted connections likely misled consumers regarding the objectivity of the paid testimonials.

292. ~~307.~~ The Manufacturer (“Marketing”) Defendants utilized many KOLs, including many of the same ones. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL the Manufacturer (“Marketing”) Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

293. ~~308.~~ Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society (“APS”) / American Academy of Pain Medicine (“AAPM”) Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation (“APF”), an advocacy organization almost entirely funded by the Manufacturer (“Marketing”) Defendants.

294. ~~309.~~ Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that “the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely watched program, broadcast nationwide, Dr. Portenoy claimed:

Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of

substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.

295. ~~310.~~ Dr. Portenoy later admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” Notably, his lectures falsely claimed that fewer than 1% of patients would become addicted to opioids.

296. ~~311.~~ According to Dr. Portenoy, because the primary goal was to “destigmatize” opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy later conceded that “[d]ata about the effectiveness of opioids does not exist.” Dr. Portenoy candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.”

297. ~~312.~~ Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of American Academy of Pain Medicine (“AAPM”) in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer (“Marketing”) Defendants (including nearly \$2 million from Cephalon).

298. ~~313.~~ During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice’s Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster’s former patients at the Lifetree Clinic died as the result of opioid overdoses.

299. ~~314.~~ Dr. Webster created and promoted the Opioid Risk Tool, a five question,

one- minute screening tool relying on patient self-reports that purportedly allows doctors to

manage

the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

300. ~~315.~~ Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Manufacturer ("Marketing") Defendants and those under their influence and control.

301. ~~316.~~ In 2011, Dr. Webster presented, via webinar, a program sponsored by the Purdue Entities entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors throughout the Commonwealth of Kentucky.

302. ~~317.~~ Dr. Webster also was a leading proponent of the concept of "pseudo addiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Upon information and belief, the Endo Entities distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudo addiction] obviously became too much of an excuse to give patients more medication."

303. ~~318.~~ The Manufacturer (“Marketing”) Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain.

304. ~~319.~~ Under the direction and control of the Manufacturer (“Marketing”) Defendants, these “Front Groups” generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted the Manufacturer (“Marketing”) Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer (“Marketing”) Defendants.

305. ~~320.~~ These Front Groups depended on the Manufacturer (“Marketing”) Defendants for funding and, in some cases, for survival. The Manufacturer (“Marketing”) Defendants exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, the Manufacturer (“Marketing”) Defendants ensured the Front Groups would generate only the messages that the Manufacturer (“Marketing”) Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members.

306. ~~321.~~ In particular, the Endo Entities, Purdue Entities controlled by the Sackler Defendants, Johnson & Johnson Entities, and Teva Entities each utilized multiple Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society (“APS”), American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), the Center for Practical Bioethics (“CPB”), the U.S. Pain Foundation

307. ~~322.~~ The most prominent of the Manufacturer (“Marketing”) Defendants’ Front Groups was the American Pain Foundation (“APF”), which, upon information and belief, received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from the Endo Entities and Purdue Entities. APF issued education guides for consumers, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their “right” to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach the Commonwealth of Kentucky.

308. ~~323.~~ In 2009 and 2010, more than 80% of APF’s operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from the Endo Entities, Purdue Entities, and Teva Entities, Cephalon, Endo, and others to avoid using its line of credit.

309. ~~324.~~ APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its controlling sponsors. Upon information and belief, APF was often called upon to provide “patient representatives” for the Manufacturer (“Marketing”) Defendants’ promotional activities, including for the Purdue Entities’ *Partners*

Against Pain and Janssen's Let's Talk Pain.

310. ~~325.~~ APF functioned largely as an advocate for the interests of the Manufacturer ("Marketing") Defendants, not patients or the public. Indeed, upon information and belief, as early as 2001, the Purdue Entities informed APF that the basis of a grant was the Purdue Entities' desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

311. ~~326.~~ Plaintiffs are informed, and believe, that on several occasions, representatives of the Manufacturer ("Marketing") Defendants, often during informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

312. ~~327.~~ The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and the Manufacturer ("Marketing") Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

313. ~~328.~~ Another front group for the Manufacturer ("Marketing") Defendants was the American Academy of Pain Medicine ("AAPM"). With the assistance, prompting, involvement, and funding of the Manufacturer ("Marketing") Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the

314. ~~329.~~ AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM’s marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an “exclusive venue” for offering education programs to doctors.

315. ~~330.~~ Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. The Endo Entities, Purdue Entities, and Teva Entities were members of the council and presented deceptive programs to doctors who attended this annual event.

316. ~~331.~~ Upon information and belief, AAPM is viewed internally by the Endo Entities as “industry friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM’s presidents have included top industry supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM even while he was the subject of a DEA investigation.

317. ~~332.~~ The Manufacturer (“Marketing”) Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

318. ~~333.~~ In 1996, AAPM and APS jointly issued a consensus statement entitled “*The Use of Opioids for the Treatment of Chronic Pain*,” endorsing opioids to treat chronic pain and claiming the risk of a patients’ addiction to opioids was low.

319. ~~334.~~ Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for the Purdue Entities at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained.

320. ~~335.~~ AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Treatment guidelines have been relied upon by doctors, especially the general practitioners and family doctors targeted by the Manufacturer ("Marketing") Defendants. Treatment guidelines not only directly inform doctors' prescribing practices but are cited throughout the scientific literature and referenced by third party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by the Manufacturer ("Marketing") Defendants discussed treatment guidelines with doctors during individual sales visits.

321. ~~336.~~ At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received direct financial support from the Manufacturer ("Marketing") Defendants.

322. ~~337.~~ The 2009 Guidelines promoted opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and concluded the risk of addiction was manageable for end-users regardless of past abuse histories.

323. ~~338.~~ One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer ("Marketing") Defendants, made to

the sponsoring organizations and committee members.

324. ~~339.~~ These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in the Commonwealth of Kentucky during the relevant time period, are still available online, and were reprinted in the Journal of Pain.

325. ~~340.~~ The Manufacturer (“Marketing”) Defendants widely referenced and promoted the 2009 Guidelines *without* disclosing the lack of evidence to support them or the Manufacturer

(“Marketing”) Defendants financial support to members of the panel.

326. ~~341.~~ The Manufacturer (“Marketing”) Defendants coordinated their efforts, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, they combined their efforts through the Pain Care Forum (“PCF”), which began in 2004 as an APF project.

327. ~~342.~~ PCF is comprised of representatives from the Manufacturer (“Marketing”) Defendants opioid manufacturers—including the Endo, Johnson & Johnson, Purdue, and Teva Entities—and various Front Groups, almost all of which received substantial financial funding from the Manufacturer (“Marketing”) Defendants.

328. ~~343.~~ Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer (“Marketing”) Defendants determined would reduce physician prescription rates and corresponding result in lower sales and profits.

2. The Manufacturer (“Marketing”) Defendants’ Coordinated Marketing Scheme Misrepresented the Significant Risks of Opioids.

a. The Manufacturer (“Marketing”) Defendants engaged in a coordinated campaign of false, deceptive, and unfair assurances grossly understating and misstating the dangerous addiction risks of the opioid drugs.

329. ~~344.~~ To falsely assure prescribers, end-users, and the public opioids were safe, the Manufacturer (“Marketing”) Defendants deceptively trivialized and failed to disclose the significant risks of long-term opioid use—particularly the high risk of addiction—through a series of orchestrated misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that:

- ☐ starting patients on opioids was low risk because most patients would not become addicted, and because those at greatest risk for addiction could be identified and managed;
- ☐ patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs;
- ☐ the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and
- ☐ abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive.

330. ~~345.~~ The Manufacturer (“Marketing”) Defendants have not only failed to correct these misrepresentations, they continue to make them today.

331. ~~346.~~ Several of the Manufacturer (“Marketing”) Defendants, including the Endo and Purdue Entities, entered into settlement agreements with public entities that expressly prohibited them from continuing to make many of the misrepresentations identified in this Complaint. Yet each Manufacturer (“Marketing”) Defendant continued to misrepresent the risks

of long-term

opioid use in the Commonwealth of Kentucky.

332. ~~347.~~ Further examples of the Manufacturer (“Marketing”) Defendants’

false, deceptive, and unfair claims about the purportedly low risk of addiction include:

- Actavis’s predecessor had a patient education brochure distributed in 2003—“*Managing Chronic Back Pain*”—that admitted opioid addiction was possible, but falsely claimed that it is “less likely if you have never had an addiction problem.” Based on Actavis’s acquisition of its predecessor’s marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.
- The Purdue and Teva Entities sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.
- The Endo Entities sponsored a website, “~~Pain~~ ~~Knowledge~~ PainKnowledge,” which, upon information and belief, claimed in 2009 that “[p]eople who take opioids as prescribed usually do not become addicted.” Upon information and belief, another Endo website, *PainAction.com*, stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.” Endo also distributed an “*Informed Consent*” document on *PainAction.com* that misleadingly suggested that only people who “have problems with substance abuse and addiction” are likely to become addicted to opioid medications.
- Upon information and belief, the Endo Entities distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: “Most health care providers who treat people with pain agree that most people do not develop an addiction problem.”
- The Johnson & Johnson Entities reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.”
- The Johnson & Johnson Entities maintained a website entitled *Prescriberesponsibly.com* that claimed any concerns about opioid addiction were “overestimated.”

- The Purdue Entities sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction."

333. ~~348.~~ Consistent with the Manufacturer ("Marketing") Defendants' published marketing materials, upon information and belief, detailers on behalf of the Endo, Johnson & Johnson, Purdue, and Teva Entities minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above—doing so throughout the Commonwealth of Kentucky.

334. ~~349.~~ Notably, in seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer ("Marketing") Defendants' Front Groups APF and NFP argued in an amicus brief to the U.S. 4th Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.

335. ~~350.~~ These claims were and remain contrary to longstanding scientific evidence. A 2016 opioid prescription guideline issued by the CDC (the "*2016 CDC Guideline*") explained that there is "[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .)." The *2016 CDC Guideline* further explained that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."

336. ~~351.~~ The FDA further exposed the Manufacturer ("Marketing") Defendants' claims about the low risk of addiction were false when it announced changes to the labeling

requirements for extended-release and long-acting (“ER/LA”) opioids in 2013 and for immediate

release (“IR”) opioids in 2016.

337. ~~352.~~ In its announcements, the FDA found “most opioid drugs have ‘high potential for abuse’” and opioids “are associated with a substantial risk of misuse, abuse, NWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed.

338. ~~353.~~ The State of New York, in a 2016 settlement agreement with the Endo Entities, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.”

339. ~~354.~~ The Endo Entities had represented to the public on their *opana.com* website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.” The State of New York found that Endo had no evidence for that statement. As a result of the finding and settlement, the Endo Entities agreed not to “make statements that . . . opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. The Endo Entities remained free to continue their false statements in other states, including the Commonwealth of Kentucky.

340. ~~355.~~ In addition to mischaracterizing the highly addictive nature of opioids, the Manufacturer (“Marketing”) Defendants sought to foster a fundamental misunderstanding of the

signs of addiction. Specifically, the Manufacturer (“Marketing”) Defendants misrepresented, to

prescribers and end-users, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain—*pseudo-addiction*—and instructed doctors to *increase* the opioid prescription dosage for end users who were already in danger of permanent addiction.

341. ~~356.~~ Pseudo-addiction was a term coined by the Purdue Entities, specifically employee Dr. David Haddox. KOL Dr. Portenoy popularized the term. Examples of the false, misleading, deceptive, and unfair statements regarding pseudo-addiction include:

- ☐ The Purdue and Teva Entities sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of *pseudo-addiction*, rather than true addiction. The 2012 edition, which remains available for sale online, continued to represent to the public that pseudo-addiction was real.
- ☐ The Johnson & Johnson Entities sponsored, funded, and edited the *Let’s Talk Pain* website, which in 2009 stated: “pseudo-addiction . . . refers to patient behaviors that may occur when pain is under-treated . . . Pseudo-addiction is different from true addiction because such behaviors can be resolved with effective pain management.”
- ☐ The Endo Entities sponsored a National Initiative on Pain Control (“NIPC”) CME program in 2009 entitled “*Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*,” which, upon information and belief, promoted pseudo-addiction by teaching that a patient’s aberrant behavior was the result of untreated pain. The Endo Entities appear to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- ☐ The Purdue Entities published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, that upon information and belief, described pseudo-addiction as a concept that “emerged in the literature” to describe the inaccurate interpretation of [drug- seeking behaviors] in end-users who have pain that has not been effectively treated.
- ☐ Upon information and belief, the Purdue Entities sponsored a CME program titled “*Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*.” In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that

because of pseudo-addiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” Instead, the doctor treats this patient by prescribing a high-dose, long-acting opioid.

342. ~~357.~~ In the 2016 CDC Guideline, the CDC rejected the validity of the pseudo-addiction fallacy invented by the Purdue Entities as a means of increasing their sales of opioid drugs to already addicted end-users.

343. ~~358.~~ In addition to misstating the addiction risk and inventing the pseudo-addiction falsehood, a third category of false, deceptive, and unfair practice is the Manufacturer (“Marketing”) Defendants’ false instructions that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction.

344. ~~359.~~ These misrepresentations were especially insidious because the Manufacturer (“Marketing”) Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids.

345. ~~360.~~ The Manufacturer (“Marketing”) Defendants’ misrepresentations made these prescribers feel more comfortable prescribing opioids to end-users, and end-users more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

- ☐ The Endo Entities paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo’s speakers bureau in 2010. The supplement *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming end-users at high risk of addiction could safely receive opioid therapy using a “maximally structured approach” involving toxicology screens and pill counts.
- ☐ The Purdue Entities, upon information and belief, sponsored a 2011 webinar, *Managing Patient’s Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent “overuse of prescriptions” and “overdose deaths.”

- As recently as 2015, upon information and belief, the Purdue Entities represented in scientific conferences that “bad apple” patients—not opioids—were the source of the addiction crisis and that once those “bad apples” were identified, doctors could safely continue prescribing opioids without the risk of addiction.

346. ~~361.~~ The 2016 CDC Guideline exposed the Manufacturer (“Marketing”) Defendants’ claims as false. The Guideline explained that there were no studies assessing the effectiveness of risk mitigation strategies “for improving outcomes related to overdose, addiction, abuse or misuse.”

347. ~~362.~~ A fourth category of deceptive messaging regarding dangerous opioids is the Manufacturer (“Marketing”) Defendants’ false assurances regarding the alleged ease of eliminating opioid dependence.

348. ~~363.~~ The Manufacturer (“Marketing”) Defendants falsely claimed opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use.

349. ~~364.~~ In truth, the 2016 CDC Guideline explained the symptoms of opioid withdrawal included severe physical and mental complications: abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion and premature labor in pregnant women.

350. ~~365.~~ The Manufacturer (“Marketing”) Defendants nonetheless continued their coordinated and deceptive marketing efforts, including continuing to downplay the severity of opioid detoxification. For example, upon information and belief, a CME sponsored by the Endo Entities, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be

351. ~~366.~~ The Purdue Entities sponsored APF's *A Policymaker's Guide to Understanding*

Pain & Its Management, which claimed that “[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation” without mentioning any hardships that might occur.

352. ~~367.~~ A fifth category of false, deceptive, and unfair statements the Manufacturer (“Marketing”) Defendants made to sell more drugs is that opioid dosages could be increased indefinitely without added risk. The ability to escalate dosages was critical to their efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. The Manufacturer (“Marketing”) Defendants’ deceptive claims include.

- ☐ Upon information and belief, Actavis’s predecessor created a patient brochure for Kadian in 2007 that stated, “Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction.” Based on Actavis’s acquisition of its predecessor’s marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond.
- ☐ The Purdue and Teva Entities sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which claimed that some patients “need” a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have “no ceiling dose” and insinuated that they are therefore the most appropriate treatment for severe pain. This publication is still available online.
- ☐ The Endo Entities sponsored a website, “*Pain Knowledge*,” that, upon information and belief, claimed in 2009 that opioid dosages may be increased until “you are on the right dose of medication for your pain.”
- ☐ The Endo Entities also distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked “If I take the opioid now, will it work later when I really need it?” The marketing response was, “The dose can be increased ... You won’t ‘run out’ of pain relief.”

The Johnson & Johnson Entities sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage

limitations as “disadvantages” of other pain medicines but omitted any discussion of risks of increased opioid dosages.

- Upon information and belief, the Purdue Entities’ *In the Face of Pain* website promoted the notion that if a patient’s doctor did not prescribe what, in the patient’s view, was a sufficient dosage of opioids, he or she should find another doctor who would—encouraging doctor shopping.
- The Purdue Entities also sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which taught that dosage escalations are “sometimes necessary,” and that “the need for higher doses of medication is not necessarily indicative of addiction,” but inaccurately downplayed the risks from high opioid dosages.
- In 2007, the Purdue Entities sponsored a CME entitled “*Overview of Management Options*” that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, were unsafe at high dosages.
- Despite their prior regulatory settlements in 2007, in 2015 the Purdue Entities presented a 2015 paper at the *College on the Problems of Drug Dependence*, “the oldest and largest organization in the U.S. dedicated to advancing a scientific approach to substance use and addictive disorders,” challenging the correlation between opioid dosage and overdose.
- Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer (“Marketing”) Defendants’ Front Groups APF and NFP argued in an amicus brief to the United States Fourth Circuit Court of Appeals that “there is no ‘ceiling dose’” for opioids.

353. ~~368.~~ Once again, the 2016 CDC Guideline confirmed the Manufacturer (“Marketing”) Defendants’ representations regarding opioids lacked, and were unsupported by, any scientific evidence. The 2016 CDC Guideline was clear that the “[b]enefits of high-dose opioids for chronic pain are not established” while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.”

~~369.~~ The CDC explained “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC stated there is an

increased risk “for opioid use disorder, respiratory depression, and death at higher dosages.” As a result, the CDC advised doctors to “avoid increasing dosage” to above 90 morphine milligram equivalents per day.

354. ~~370.~~ The Manufacturer (“Marketing”) Defendants’ coordinated and deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that opioids can cure addiction and abuse.

355. ~~371.~~ The Manufacturer (“Marketing”) Defendants made misleading claims about the efficacy of their *abuse-deterrent* opioid formulations. For example, Endo’s advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant suggesting it would be more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets’ “extended-release features can be compromised, causing the medication to ‘dose dump,’ when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing.” Opana ER was also noted to be susceptible to abuse by snorting and could be “readily prepared for injection.” The letter discussed “the troubling possibility that a higher (and rising) percentage of [Opana ER Extended- Release Tablet] abuse is occurring via injection.”

356. ~~372.~~ The Endo Entities’ own studies, which it failed to disclose, recognized that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

b. The Manufacturer (“Marketing”) Defendants engaged in a coordinated campaign of false, deceptive, and unfair assurances grossly overstating the benefits of the opioid drugs.

~~373.~~ To convince prescribers, end-users, and the public opioids were appropriate for treating chronic pain, the Manufacturer (“Marketing”) Defendants also had to persuade them of

the benefits of long-term opioid use. The Manufacturer (“Marketing”) Defendants’ efforts and representations were directly contrary to the CDC Guideline and the FDA findings.

357. ~~374.~~ The CDC Guideline stated, “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use.

358. ~~375.~~ The FDA recognized the lack of evidence to support long-term opioid use. Despite this, Manufacturer (“Marketing”) Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly continued to market opioids as appropriate for—and supported by scientific evidence—long-term use in treating chronic pain. Examples of the Manufacturer (“Marketing”) Defendants’ false claims included:

- ☐ Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health,” and help patients enjoy their lives.
- ☐ The Endo Entities distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- ☐ The Johnson & Johnson Entities sponsored and edited a patient education guide *Finding Relief: Pain Management for Older Adults* (2009) – which stated as “a fact” that “opioids may make it easier for people to live normally.” The guide listed expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

The Johnson & Johnson Entities promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors’ offices, of presumed patients in active professions; the caption read, “Pain doesn’t fit into their schedules.”

- ☐ Upon information and belief, the Purdue Entities ran a series of advertisements for OxyContin in 2012 in medical journals entitled

“Pain vignettes,” which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improved patients’ function.

- ☐ Responsible Opioid Prescribing (2007), sponsored and distributed by the Endo, Purdue, and Teva Entities, taught that relief of pain by opioids, by itself, improved patients’ function.
- ☐ The Purdue and Teva Entities sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids “give [pain patients] a quality of life we deserve.” This publication is still available online.
- ☐ The Endo Entities’ NIPC website “Pain Knowledge” claimed in 2009, upon information and belief, that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” Elsewhere, the website touted improved quality of life (as well as “improved function”) as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make misleading claims about function, and Endo closely tracked visits to the site.
- ☐ The Endo Entities were the sole sponsor, through NIPC, of a series of CMEs entitled “*Persistent Pain in the Older Patient*.” Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.”
- ☐ The Johnson & Johnson Entities sponsored and funded a multimedia patient education campaign called “*Let’s Talk Pain*.” One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the “*Let’s Talk Pain*” campaign, featured an interview edited by The Johnson & Johnson Entities claiming that opioids allowed a patient to “continue to function.”

The Purdue Entities sponsored the development and distribution of APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “[m]ultiple clinical studies” have shown that opioids are effective in improving “[d]aily function,” “[p]sychological health,” and “[o]verall health-related quality of life for chronic pain.” The Policymaker’s Guide was originally published in 2011.

- ☐ The Endo, Johnson & Johnson, Purdue, and Teva Entities' sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

359. ~~376.~~ As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that “we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”

360. ~~377.~~ In 2008, upon information and belief, the FDA issued a warning letter that “[the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”

361. ~~378.~~ The Manufacturer (“Marketing”) Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that prescribers, end-users, and the public would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Manufacturer (“Marketing”) Defendants contravened pronouncements by, and guidance from, the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort “in patients for which alternative treatment options” like non-opioid drugs “are inadequate.”

~~379.~~ The 2016 CDC Guideline stated NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

362. ~~380.~~ The Purdue Entities misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours—a fact the Purdue Entities have known at all times relevant to this action.

363. ~~381.~~ Upon information and belief, the Purdue Entities’ own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as “end of dose” failure, and the FDA found in 2008 that a “substantial proportion” of chronic pain patients taking OxyContin experience it. This not only renders Purdue’s promise of 12-hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief end-users experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

364. ~~382.~~ The Purdue Entities’ competitors were aware of this problem. For example, upon information and belief, the Endo Entities ran advertisements for Opana ER referring to “real” 12- hour dosing.

365. ~~383.~~ Nevertheless, the Purdue Entities falsely promoted OxyContin as if it were effective for a full 12 hours. Upon information and belief, Purdue’s sales representatives continue to tell prescribers that OxyContin lasts a full 12 hours.

~~384.~~ Front Groups supported by the Purdue Entities likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain

Initiative in support of the Purdue Entities, those amici represented:

OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.

366. ~~385.~~ The Teva Entities deceptively marketed their opioids Actiq and Fentora for chronic pain even though the FDA expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful *fentanyl-based* IR opioids. Neither is approved, nor been shown to be safe or effective, for treating chronic pain.

367. ~~386.~~ The FDA expressly prohibited the Teva Entities from marketing Actiq for anything but cancer pain and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of “serious and life-threatening adverse events” and abuse—which are greatest in non-cancer treating end-users.

368. ~~387.~~ The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should *only* be used for cancer treating end-users who are opioid-tolerant and should *not* be used for any other conditions, such as migraines, post-operative pain, or pain due to injury. The FDA advised that Fentora “is only approved for breakthrough cancer pain in patients who are opioid-tolerant, meaning those patients who take a regular, daily, around-the-clock narcotic pain medication.”

~~388.~~ Despite this, the Teva Entities conducted and continued to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was *not* approved, inappropriate, and unsafe. As part of their campaign, the Teva

Entities used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- They paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors “[c]linically, broad classification of pain syndromes as either cancer or non-cancer related has limited utility” and recommended Actiq and Fentora for patients with chronic pain.
- Upon information and belief, their sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.
- In December 2011, they widely disseminated a journal supplement entitled “*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*” to Anesthesiology News, Clinical Oncology News, and Pain Medicine News—three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promoted Fentora for “multiple causes of pain”—and not just for cancer pain.

369. ~~389.~~ The Teva Entities’ deceptive marketing gave prescribers, end-users, and the public the false impression that Actiq and Fentora were safe and effective for treating chronic pain and also approved by the FDA for such uses. Again, this was false.

~~390.~~ The Purdue Entities also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Their sales representatives maintained a database since at least 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as it was legally required) or to cease marketing to them, the Purdue Entities used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin it had promoted as less addictive—in order to persuade the FDA to bar the manufacture and sale of

generic copies of the drug because the drug was too likely to be abused.

370. ~~391.~~ In an interview with the Los Angeles Times, a Purdue Entity senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take any action even where its employees personally witnessed the diversion of its drugs.

371. ~~392.~~ The same was true of prescribers. Despite its knowledge of illegal prescribing, the Purdue Entities did not report that a Los Angeles clinic prescribed *more than 1.1 million*

OxyContin tablets and that its district manager described the clinic internally as “an organized drug ring.” Instead, the Purdue Entities sought to protect their own sales and profits—again at the expense of the end-users, the public, and ultimately the Plaintiffs.

372. ~~393.~~ Similar to the Purdue Entities, the Endo Entities have been cited for their failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with the Endo Entities the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

3. The Manufacturer (“Marketing”) Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

~~394.~~ As a part of their deceptive marketing scheme, the Manufacturer (“Marketing”) Defendants identified and targeted susceptible prescribers and vulnerable end-user populations in the U.S., including within the Commonwealth of Kentucky. For example, the Manufacturer (“Marketing”) Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain end-users and prescribe opioids but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to

accept and to rely on the Manufacturer (“Marketing”) Defendants’ misrepresentations.

373. ~~395.~~ The Manufacturer (“Marketing”) Defendants also targeted vulnerable end-user populations like the elderly and veterans, who tend to suffer from chronic pain. The Manufacturer (“Marketing”) Defendants targeted these vulnerable end-users even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observed that existing evidence confirmed elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages. The 2016 CDC Guideline concluded there must be “additional caution and increased monitoring” to minimize the risks of opioid use in elderly end-users. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

4. The Manufacturer (“Marketing”) Defendants made Materially Deceptive Statements and Concealed Material Facts.

374. ~~396.~~ As alleged herein, the Manufacturer (“Marketing”) Defendants made and disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids.

375. ~~397.~~ The Manufacturer (“Marketing”) Defendants’ actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

376. ~~398.~~ The Purdue Entities made and/or disseminated deceptive statements, and concealed material facts in such a way as to make their statements deceptive, including, but not limited to, the following:

Creating, sponsoring, and assisting in the distribution of end-user education materials distributed to consumers that contained deceptive statements;

- ☐ Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- ☐ Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudo-addiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- ☐ Distributing brochures to prescribers, end-user, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- ☐ Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudo-addiction, even for high-risk patients;
- ☐ Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- ☐ Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- ☐ Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- ☐ Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- ☐ Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- ☐ Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;
- ☐ Creating, endorsing, and supporting the distribution of prescriber and end-user education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- ☐ Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- ☐ Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- ☐ Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- ☐ Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing; and
- ☐ Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

377. ~~399.~~ The Endo Entities made and/or disseminated deceptive statements, and concealed material facts in such a way as to make their statements deceptive, including, but not limited to, the following:

- ☐ Creating, sponsoring, and assisting in the distribution of end-user education materials that contained deceptive statements;

Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

- ☐ Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- ☐ Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- ☐ Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudo-addiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- ☐ Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- ☐ Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- ☐ Providing needed financial support to pro-opioid pain organizations – including over \$5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- ☐ Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- ☐ Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- ☐ Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudo-addiction;

- ☐ Creating, endorsing, and supporting the distribution of prescriber and end-user education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and
- ☐ Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

378. ~~400.~~ The Johnson & Johnson Entities made and/or disseminated deceptive statements, and concealed material facts in such a way as to make their statements deceptive, including, but not limited to, the following:

- ☐ Creating, sponsoring, and assisting in the distribution of end-user education materials that contained deceptive statements;
- ☐ Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- ☐ Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudo-addiction through internet sites over which Janssen exercised final editorial control and approval;
- ☐ Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- ☐ Sponsoring, directly distributing, and assisting in the dissemination of end-user education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- ☐ Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in end-user education materials, concerning the use of opioids to treat chronic non-cancer

pain;

- ☐ Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- ☐ Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- ☐ Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- ☐ Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudo-addiction;
- ☐ Creating, endorsing, and supporting the distribution of prescriber and end-user education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- ☐ Targeting veterans by sponsoring and disseminating end-user education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and
- ☐ Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

379. ~~401.~~ The Teva Entities made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way as to make their statements deceptive, including, but not limited to, the following:

Creating, sponsoring, and assisting in the distribution of end-user education materials that contained deceptive statements;

- ☐ Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudo-addiction, even for high-risk end-users;
- ☐ Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- ☐ Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;
- ☐ Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- ☐ Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- ☐ Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;
- ☐ Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain treating end-users;
- ☐ Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and
- ☐ Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

402. The Allergan Entities made and/or disseminated deceptive statements, and concealed material facts in such a way as to make their statements deceptive, including, but not limited to, the following:

- ☐ Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- ☐ Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- ☐ Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- ☐ Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

5. The Manufacturer (“Marketing”) Defendants Fraudulently Concealed Their Misconduct.

380. ~~403.~~ The Manufacturer (“Marketing”) Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the significant risks and illusory benefits of using opioids for chronic pain—even though they were fully aware and knew their representations were false and deceptive.

381. ~~404.~~ The history of opioids, as well as research and clinical experience establish that opioids are highly addictive and are responsible for a litany of serious adverse outcomes.

382. ~~405.~~ The FDA warned the Manufacturer (“Marketing”) Defendants of these facts. Manufacturer (“Marketing”) Defendants had ready access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and death—all of which clearly described the significant harm from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers.

~~406.~~ The Manufacturer (“Marketing”) Defendants were further aware of pronouncements from the FDA and CDC based on medical evidence that conclusively exposed the falsity of Manufacturer (“Marketing”) Defendants’ representations—with the Endo and

Purdue Entities entering into agreements in New York that prohibited them from continuing to make the same misrepresentations described in this Complaint.

383. ~~407.~~ At all times relevant to this Complaint, the Manufacturer (“Marketing”) Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer (“Marketing”) Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs.

384. ~~408.~~ The Manufacturer (“Marketing”) Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer (“Marketing”) Defendants’ false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain.

385. ~~409.~~ The Manufacturer (“Marketing”) Defendants never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties.

386. ~~410.~~ The Manufacturer (“Marketing”) Defendants exerted considerable influence on these promotional and “educational” materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, *PainKnowledge.org*, which is run by the NIPC, did not disclose the Endo Entities’ involvement. Other Manufacturer (“Marketing”) Defendants, such as the Johnson & Johnson and Purdue Entities, ran similar websites that masked their own role.

~~411.~~ The Manufacturer (“Marketing”) Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not.

387. ~~412.~~ The Manufacturer (“Marketing”) Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support.

388. ~~413.~~ The Manufacturer (“Marketing”) Defendants invented “pseudo-addiction” and promoted it to an unsuspecting medical community.

389. ~~414.~~ The Manufacturer (“Marketing”) Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction.

390. ~~415.~~ The Manufacturer (“Marketing”) Defendants recommended to the medical community that dosages be increased, without disclosing the risks.

391. ~~416.~~ The Manufacturer (“Marketing”) Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids’ alleged benefits, disguising the risks, and promoting sales.

392. ~~417.~~ The lack of support for the Manufacturer (“Marketing”) Defendants’ deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the Plaintiffs.

393. ~~418.~~ The Manufacturer (“Marketing”) Defendants successfully concealed from the medical community, end-users, and health care payors facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert.

~~419.~~ Plaintiffs did not, and could not, know of the existence or scope of the Manufacturer (“Marketing”) Defendants’ industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

C. The Wholesale Distributor Defendants’ Unlawful Sale and Distribution of Opioids.

394. ~~420.~~ The Wholesale Distributor Defendants owe a duty under Kentucky law to

monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating within the Commonwealth of Kentucky. The duty also included those opioid orders the Wholesale Distributor Defendants knew or should have known were likely to be diverted into the Commonwealth of Kentucky.

395. ~~421.~~ The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

396. ~~422.~~ Each of the Wholesale Distributor Defendants repeatedly and purposefully breached its duties under Kentucky law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into the Commonwealth of Kentucky.

397. ~~423.~~ The unlawful diversion of prescription opioids is a direct and proximate cause and/or substantial contributing factor to the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the Commonwealth of Kentucky.

398. ~~424.~~ This diversion and the epidemic are direct and proximate cause of the harm and injury for which Plaintiffs seek relief. The opioid epidemic in the Commonwealth of Kentucky remains an immediate hazard to public health and safety.

399. ~~425.~~ The resulting opioid epidemic is a temporary and continuous public nuisance and remains unabated.

400. ~~426.~~ The Wholesale Distributor Defendants' intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the resulting harms and damages alleged herein.

1. Wholesale Distributor Defendants’ Have a Duty to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders.

401. ~~427.~~ In the Commonwealth of Kentucky, opioids are a Schedule II controlled substance because they have a “high potential for abuse” and the potential to cause “severe psychic or physical dependence” and/or “severe psychological . . . dependence.”

402. ~~428.~~ As wholesale drug distributors, each Wholesale Distributor Defendant was required to first be licensed by the Kentucky Cabinet for Health and Family Services. To receive and maintain this license, each Wholesale Distributor Defendant assumed a duty to comply with “all applicable federal and state laws and regulations relating to controlled substances.”

403. ~~429.~~ Each Wholesale Distributor Defendant was further required to be licensed by the Kentucky Board of Pharmacy. To receive and maintain this license, each of the Wholesale Distributor Defendants assumed a duty to “demonstrates or continues to demonstrate acceptable operational procedures, including . . . compl[iance] with all DEA regulations.”

404. ~~430.~~ Kentucky prohibits a licensed pharmacy wholesale distributor from “[k]nowing or having reason to know that a pharmacist, pharmacist intern, or pharmacy technician has engaged in or aided and abetted the unlawful distribution of [controlled substances] and failing to report any relevant information to the board.”

405. ~~431.~~ Failing to report known or suspected unlawful distribution of controlled substances may subject a pharmacy wholesale distributor to denial, non-renewal, suspension or revocation of their license, among other penalties.

406. ~~432.~~ Additionally, Kentucky’s minimum requirements for wholesale drug distribution mandate that “all sales and distributions shall be in accordance with . . . the federal

controlled substances laws.”

1376

407. ~~433.~~ Each of the Wholesale Distributor Defendants was further required to register with the DEA, pursuant to the federal Controlled Substance Act as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Those requirements were adopted and incorporated into Kentucky law.

408. ~~434.~~ Each of the Wholesale Distributor Defendants has an affirmative duty under Kentucky law (incorporating federal requirements) to act as a gatekeeper guarding and protecting the public against the diversion of highly addictive and dangerous opioids. This gatekeeping requirement includes creating, maintaining, and enforcing “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” Again, these requirements have been adopted and incorporated into Kentucky law.

409. ~~435.~~ Kentucky declared “[t]he regulation of controlled substances in this Commonwealth is important and necessary for the preservation of public safety and public health.” Kentucky further declared “effective control and regulation” of all “persons who are required to obtain a license, certificate, or permit from the Board of Pharmacy, whether located in or outside the Commonwealth, that distribute, manufacture, or sell drugs within the Commonwealth” is necessary in order to “promote, preserve, and protect public health, safety, and welfare.”

410. ~~436.~~ The Kentucky Board of Pharmacy regulations state that “[a] wholesale distributor shall not . . . operate in a manner that endangers the public health.” The federal regulations incorporated by Kentucky law impose a non-delegable duty upon wholesale drug distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the

Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

411. ~~437.~~ “Suspicious orders” include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter, and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor’s customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

412. ~~438.~~ In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels.

413. ~~439.~~ These prescription drugs are regulated for the purpose of providing a “closed” system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.

414. ~~440.~~ Different entities supervise the discrete links in the chain that separate a consumer

from a controlled substance. Statutes and regulations define each participant's role and responsibilities. As the DEA advised the Wholesale Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."

415. ~~441.~~ The Wholesale Distributor Defendants have admitted that they are responsible for reporting suspicious orders.

416. ~~442.~~ The DEA sent a letter to each of the Wholesale Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly stated that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The letter also instructed that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes." The DEA warned that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

417. ~~443.~~ The DEA sent a second letter to each of the Wholesale Distributor Defendants on December 27, 2007. This letter reminded the Wholesale Distributor Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled

substances.” The letter further

stated:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter, and the order should be reported as suspicious. Likewise, a registrant need not wait for a “normal pattern” to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant’s customer base and the patterns throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if

the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating “excessive purchases” do not comply with the requirement to report suspicious orders, even if the registrant calls such reports “suspicious order reports.”

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824 and may result in the revocation of the registrant’s DEA Certificate of Registration.

418. ~~444.~~ Finally, the DEA letter referenced the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discussed the obligation to report suspicious orders and “some criteria to use when determining whether an order is suspicious.”

419. ~~445.~~ The Wholesale Distributor Defendants admit that they “have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs but undertake such efforts as responsible members of society.”

420. ~~446.~~ The Wholesale Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders.

421. ~~447.~~ Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical

distributors, explain that

distributors are “[a]t the center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.”

422. ~~448.~~ The guidelines set forth recommended steps in the “due diligence” process, and note in particular that if an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.

423. ~~449.~~ Each of the Wholesale Distributor Defendants sold and distributed prescription opioids, including hydrocodone and/or oxycodone, to retailers throughout the Commonwealth of Kentucky—including retailers from which the Wholesale Distributor Defendants’ knew opioids were likely to be diverted.

424. ~~450.~~ Each of the Wholesale Distributor Defendants owed a, and owes an ongoing, duty to monitor and detect suspicious orders of prescription opioids.

425. ~~451.~~ Each of the Wholesale Distributor Defendants owed a, and owes an ongoing, duty under Kentucky law to:

- ☐ investigate and refuse suspicious orders of prescription opioids;
- ☐ report suspicious orders of prescription opioids; and
- ☐ prevent the diversion of prescription opioids into illicit markets in the Commonwealth of Kentucky.

426. ~~452.~~ The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for non-medical purposes and subsequent plague of opioid addiction.

The foreseeable harm resulting from the diversion of prescription opioids for non-medical

purposes is abuse, addiction, morbidity and mortality throughout the Commonwealth of Kentucky and the damages caused thereby.

2. The Wholesale Distributor Defendants Breached their Legal Duties.

427. ~~453.~~ Because the Wholesale Distributor Defendants handle such large volumes of controlled substances and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on them to create, maintain, and enforce effective controls to prevent diversion of controlled substances—any deviation from these required checks and balances results in a system collapse, in this case a foreseeable and preventable opioid epidemic.

428. ~~454.~~ The sheer volume of prescription opioids distributed to pharmacies throughout the Commonwealth of Kentucky, and/or to pharmacies from which the Wholesale Distributor Defendants knew the opioids were likely to be diverted, is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them. By way of example, the Wholesale Distributor Defendants:

- ☐ failed to report suspicious orders;
- ☐ unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency;
- ☐ breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates;
- ☐ breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels;
- ☐ breached their duty to “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and failed to inform the authorities of suspicious orders when discovered; and

- ☐ breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.

429. ~~455.~~ Kentucky's laws at issue here are, and for which the Wholesale Distributor Defendants are required and obligated to comply, are expressly for the protection of the public.

The practice of pharmacy within the Commonwealth is declared to be a professional practice affecting the public health, safety, and welfare, and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this chapter, should merit and receive the confidence of the public, and only qualified persons shall be permitted to engage in the practice of pharmacy and ensure the quality of drugs and related devices distributed within the Commonwealth. This chapter shall be liberally construed to carry out these objectives and purposes. The persons entrusted through this chapter to engage in the practice of pharmacy shall be pharmacists. They shall be recognized by the Commonwealth as health care professionals, and, within their statutory scope of practice, providers of pharmacy-related primary care.⁷

430. ~~456.~~ The Wholesale Distributor Defendants' violations of public safety statutes constitute prima facie evidence of negligence *per se* under Kentucky law.

431. ~~457.~~ The Wholesale Distributor Defendants knowingly, willfully, intentionally, and recklessly sold and distributed prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market—all with intent of increasing their respective sales and profits.

432. ~~458.~~ The Wholesale Distributor Defendants acted with actual malice and reckless disregard in breaching their duties, i.e., they have acted with a conscious disregard for the rights

⁷ See KRS 415.002.

and safety of the citizens of the Commonwealth of Kentucky—said actions resulting the substantial social and economic harm, the opioid epidemic.

433. ~~459.~~ The Wholesale Distributor Defendants’ repeated shipments of suspicious orders, over an extended period of time, in violation of Kentucky’s public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and warrants an award of punitive damages.

3. The Wholesale Distributor Defendants Actively Avoided, and Willfully Misrepresented their Compliance with, their Legal Duties.

434. ~~460.~~ The Wholesale Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under Kentucky law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Wholesale Distributor Defendants’ compliance with their legal duties.

435. ~~461.~~ Wholesale Distributor Defendants have refused to recognize any duty beyond reporting suspicious orders. In *Masters Pharmaceuticals*, the HDMA – a trade association run by the Wholesale Distributor Defendants – and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. *Inaccurately* describing the legal duties, for which the wholesale drug industry has knowingly and willfully failed to comply, they:

- ☐ argued the “DEA has required distributors not only to report suspicious orders, but to investigate orders (e.g., by interrogating pharmacies and physicians) and take action to halt suspicious orders before they are filled.”
- ☐ argued the “DEA now appears to have changed its position to require that distributors not only report suspicious orders but investigate and halt suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it is changing position and show that there are good reasons for

the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications.”

- ☐ alleged (inaccurately) that nothing “requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.”
- ☐ complained that the purported “practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties.”
- ☐ alleged (inaccurately) that “DEA’s regulations [] sensibly impose[] a duty on distributors simply to report suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders.”
- ☐ argued that, “[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA’s demands.”

[436.](#) ~~462.~~ The positions taken by the trade groups is emblematic of the orchestrated and systemic collaborative efforts by the Wholesale Distributor Defendants to avoid their legal duties and obligations to prevent the diversion of opioids.

[437.](#) ~~463.~~ The Court of Appeals for the District of Columbia recently confirmed that wholesale drug distributors have duties and legal obligations *beyond reporting*. *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical’s license and determined that in addition to reporting suspicious orders, distributors must “decline to ship the order, or conduct some ‘due diligence’ and — if it is able to determine that the order is not likely to be diverted into illegal channels — ship the order.” Master Pharmaceutical was found in violation of the legal requirements because it failed to conduct necessary investigations and filled suspicious orders. A distributor’s investigation *must* dispel all the red flags giving rise to suspicious circumstance prior to shipping

a suspicious order.

438. ~~464.~~ Wholesale Distributor Defendant McKesson recently admitted to breaching its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement (“2017 Agreement”) entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters.”

439. ~~465.~~ The 2017 Agreement determined that Wholesale Distributor Defendant McKesson “distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice...”

440. ~~466.~~ Wholesale Distributor Defendant McKesson admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers ... at the McKesson Distribution Centers” including the McKesson Distribution Center located in “Washington Courthouse, Ohio.”

441. ~~467.~~ Due to these violations, Wholesale Distributor Defendant McKesson agreed that its authority to distribute controlled substances from the Washington Courthouse, Ohio facility (among other facilities) would be partially suspended.

442. ~~468.~~ The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in

which Wholesale Distributor Defendant McKesson also admitted it had failed to report suspicious orders of controlled substances. In the 2008 Settlement Agreement, McKesson “recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA,” but had failed to do so.

443. ~~469.~~ The 2017 Memorandum of Agreement confirmed that Wholesale Distributor Defendant McKesson had continued to violate its admitted legal duties by “fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders ... in accordance with McKesson’s obligations.” As a result of these ongoing violations, McKesson was fined \$150,000,000.

444. ~~470.~~ Even though it had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though it had specifically agreed in 2008 that it would no longer violate those obligations, Wholesale Distributor Defendant McKesson continued to violate its legal duties.

445. ~~471.~~ Because of the Wholesale Distributor Defendants’ refusal to comply with their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the U.S. Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders. These actions include the following:

- On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center (“Orlando Facility”) alleging failure to

maintain effective controls against diversion of controlled substances.

On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

- ☐ On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- ☐ On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- ☐ On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- ☐ On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- ☐ On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement (“2008 MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;
- ☐ On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);
- ☐ On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of oxycodone;

- On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and
- On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

446. ~~472.~~ Rather than abide by their admitted and non-delegable duties under public safety laws, the Wholesale Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act” which, ironically, raised the burden for the DEA to revoke a distributor’s license from “imminent harm” to “immediate harm” and provided the industry the right to “cure” any violations of law before a suspension order can be issued.

447. ~~473.~~ In addition to taking actions to limit regulatory prosecutions and suspensions, the Wholesale Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Wholesale Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

448. ~~474.~~ For example, Wholesale Distributor Defendant Cardinal Health claimed that it uses “advanced analytics” to monitor its supply chain and represented that it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.” Given the sales volumes and Cardinal Health’s history of

violations,

its executive was either: (i) not telling the truth; or (ii) if it actually used such a system, willfully ignored the results.

449. ~~475.~~ Similarly, Wholesale Distributor Defendant McKesson publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.” Again, given its history of repeated violations, this statement was either false or Wholesale Distributor Defendant McKesson willfully ignored the results.

450. ~~476.~~ By misleading the public about the effectiveness of their controlled substance monitoring programs, the Wholesale Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the Plaintiffs’ claims. The Plaintiffs did not know of the existence or scope of the Wholesale Distributor Defendants’ industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

451. ~~477.~~ Meanwhile, the opioid epidemic rages unabated throughout the Commonwealth of Kentucky. The epidemic continues unabated because the regulatory fines and suspensions failed to effect change in the Wholesale Distributor Defendants’ illegal and deceptive conduct. The Wholesale Distributor Defendants simply elected to treat the fines as a cost of doing business— continuing to generate billions of dollars in annual revenue and corresponding profits, at the expense of the public.

452. ~~478.~~ Moreover, even when a suspension occurs, it does little to abate the opioid epidemic. The Wholesale Distributor Defendants simply re-route their shipments to another facility using a different registration number—of which they maintain multiple.

453. ~~479.~~ The Wholesale Distributor Defendants have abandoned their duties imposed under Kentucky law, taken advantage of a lack law enforcement resources, and

abused the

privilege of distributing controlled substances in the Commonwealth of Kentucky.

D. The Manufacturer (“Marketing”) Defendants Unlawful Failure to Prevent Diversion and Failure to Monitor, Report, and Prevent Suspicious Orders.

454. ~~480.~~ The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Wholesale Distributor Defendants were also legally required of the Manufacturer (“Marketing”) Defendants under Kentucky law.

455. ~~481.~~ The Manufacturer (“Marketing”) Defendants were required to comply with the same licensing and permitting requirements as the Wholesale Distributor Defendants.

456. ~~482.~~ Like the Wholesale Distributor Defendants, the Manufacturer (“Marketing”) Defendants were required to register with Kentucky regulators with respect to their manufacture, sale, and distribution of opioids.

457. ~~483.~~ Additionally, the Manufacturer (“Marketing”) Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances. Like the Wholesale Distributor Defendants, the Manufacturer (“Marketing”) Defendants breached these duties.

458. ~~484.~~ The Manufacturer (“Marketing”) Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion.

459. ~~485.~~ The Manufacturer (“Marketing”) Defendants engaged in the practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate.

460. ~~486.~~ After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer ("Marketing") Defendants knew—just as the Wholesale

Distributor Defendants knew—the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer (“Marketing”) Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

461. ~~487.~~ Kentucky law is clear that just like opioid distributors, opioid manufacturers are required to “design and operate a system to disclose . . . suspicious orders of controlled substances” and to maintain “effective controls against diversion.”

462. ~~488.~~ By way of example, the U.S. Department of Justice reiterated the opioid manufacturers obligations to report suspicious orders—fining Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The press release accompanying the file stated that Mallinckrodt had failed to meet its obligations to detect and notify the DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone, Mallinckrodt’s actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. “Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands.”

463. ~~489.~~ Among the allegations resulting in the fine, it was noted that “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”

464. ~~490.~~ Mallinckrodt acknowledged that as part of its business model it collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to downstream registrants. Mallinckrodt agreed that, from this data, it would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”

465. ~~491.~~ The same business practices utilized by Mallinckrodt regarding “charge backs” and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer (“Marketing”) Defendants.

466. ~~492.~~ Through, inter alia, the charge back data, the Manufacturer (“Marketing”) Defendants could monitor suspicious orders of opioid but, instead:

- ☐ they failed to monitor, report, and halt suspicious orders of opioids as required by federal law;
- ☐ their failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful;
- ☐ they misrepresented their compliance with Kentucky law; and
- ☐ they enabled the supply of prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

467. ~~493.~~ The knowing, reckless and intentional illegal wrongful actions and omissions by the Manufacturer (“Marketing”) Defendants, contributed to and caused the diversion of opioids throughout the Commonwealth of Kentucky—resulting in significant financial hardship to the Plaintiffs burdened with the foreseeable effects of the opioid epidemic.

468. ~~494.~~ The Manufacturer (“Marketing”) Defendants’ knowing, reckless and intentional

illegal wrongful actions and omissions in failing to prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into the Commonwealth of Kentucky—warranting the imposition of punitive damages.

E. All Defendants Engaged in Unlawful Conduct and Breached their Legal Duties thereby Causing the Harm and Substantial Damages Alleged Herein.

469. ~~495.~~ As the Manufacturer (“Marketing”) Defendants’ efforts to expand the market for opioids increased, so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization, and death among the people of the Commonwealth of Kentucky.

470. ~~496.~~ The Wholesale Distributor Defendants have continued to unlawfully ship these massive quantities of opioids throughout the Commonwealth of Kentucky thereby fueling the opioid epidemic.

471. ~~497.~~ There is a “parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.”

472. ~~498.~~ Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions. The epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”

473. ~~499.~~ The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.

474. ~~500.~~ The opioid epidemic has escalated throughout the Commonwealth of Kentucky with devastating effects. Substantial opiate-related substance abuse, hospitalization and death that mirrors Defendants ‘continued unlawful distribution of opiates.

475. ~~501.~~ Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids, like heroin, the massive distribution of opioids throughout the Commonwealth of Kentucky and areas from which such opioids are being diverted, Defendants' actions have resulted in significant increases in addiction, abuse, and death.

476. ~~502.~~ Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety throughout the Commonwealth of Kentucky.

477. ~~503.~~ Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety throughout the Commonwealth of Kentucky.

478. ~~504.~~ Defendants repeatedly and purposefully breached their duties under Kentucky law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes throughout the Commonwealth of Kentucky.

479. ~~505.~~ The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality throughout the Commonwealth of Kentucky. This diversion and the epidemic are direct causes of foreseeable harms incurred by the Plaintiffs.

480. ~~506.~~ Defendants' intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiffs seek relief, as alleged herein. Plaintiffs also seek the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

481. ~~507.~~ Plaintiff seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

482. ~~508.~~ Plaintiff seeks economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance. To eliminate the hazard to public health and safety, and abate the public nuisance, a “multifaceted, collaborative public health and law enforcement approach is urgently needed.”

483. ~~509.~~ A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain. These community-based problems require community-based solutions that have been limited by “budgetary constraints at the state and Federal levels.”

484. ~~510.~~ Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted throughout the Commonwealth of Kentucky— such relief includes legal and equitable relief, declaratory, and injunctive relief, and disgorgement.

F. The Retail Pharmacy Defendants Were on Notice of and Contributed to the Illegal Diversion of Prescription Opioids.

485. ~~511.~~ As with the Manufacturer (“Marketing”) and Wholesale Distributor Defendants, the Retail Pharmacy Defendants earned enormous profits by flooding the Commonwealth of Kentucky with prescription opioids.

486. ~~512.~~ Similarly, as with the Manufacturer (“Marketing”) and Wholesale Distributor Defendants, the Retail Pharmacy Defendants were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as dispensaries—and in some instances also as Distributors. *See supra*. Yet, instead of taking any

meaningful action to stem the flow of opioids into Kentucky communities, the Retail Pharmacy

Defendants continued to participate in the oversupply of opioids and profit from it.

487. ~~513.~~ Each of the Retail Pharmacy Defendants does substantial business throughout the Commonwealth of Kentucky and, as such, were fully aware both of their legal obligations under Kentucky law and of the devastating impact opioids would have—on the end-users, the public, and ultimately the Plaintiffs—if left unchecked and allowed to be diverted and/or abused. Yet, the Retail Pharmacy Defendants failed to take meaningful action to stop opioid diversion despite their knowledge which in turn contributed substantially to the diversion problem in the Commonwealth of Kentucky.

488. ~~514.~~ The Retail Pharmacy Defendants developed and maintained extensive data on opioids they distributed and dispensed. Through this data, the Retail Pharmacy Defendants had direct and intimate non-public knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout Kentucky.

489. ~~515.~~ The Retail Pharmacy Defendants used this detailed and non-public data not to fulfill their legal obligations to stem the flow of opioid abuse and diversion, but instead to evaluate and to improve their own sales activities and workforce.

490. ~~516.~~ On information and belief, the Retail Pharmacy Defendants also provided the Manufacturer (“Marketing”) and Wholesale Distributor Defendants with data regarding, inter alia, individual doctors in exchange for rebates or other forms of consideration. The Retail Pharmacy Defendants’ data was and remains a high value resource that they could have used to help prevent opioid abuse and diversion—the opioid epidemic—but they made the deliberate choice not to do so and to instead focus on their own financial interests.

1. The Retail Pharmacy Defendants Have a Duty to Prevent Diversion.

491. ~~517.~~ Each participant in the supply chain of opioid distribution, including the Retail

Pharmacy Defendants, is responsible for preventing the diversion of prescription opioids into the illegal market by, among other things, monitoring, and reporting suspicious activity.

492. ~~518.~~ The Retail Pharmacy Defendants, like the Manufacturer (“Marketing”) and Wholesale Distributor Defendants, are registrants under the CSA and Kentucky’s CSA. Under the CSA, and correspondingly Kentucky law, pharmacy registrants are required to “provide effective controls and procedures to guard against theft and diversion of controlled substances.”

493. ~~519.~~ The regulations expressly state that “[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” Because the Retail Pharmacy Defendants themselves are registrants under the CSA and Kentucky’s CSA, they have the corresponding duty to prevent diversion.

494. ~~520.~~ The DEA, among others, has provided extensive guidance to the Retail Pharmacy Defendants concerning their duties to the public. The guidance expressly directs them on how to identify suspicious orders and other evidence of diversion.

495. ~~521.~~ Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others. Additional types of suspicious orders include:

- ☐ prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area;
- ☐ prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis;
- ☐ prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time;

- ☐ prescriptions that look “too good” or where the prescriber’s handwriting is too legible;
- ☐ prescriptions with quantities or doses that differ from usual medical usage;
- ☐ prescriptions that do not comply with standard abbreviations and/or contain no abbreviations;
- ☐ photocopied prescriptions; and/or
- ☐ prescriptions containing different handwriting.

496. ~~522.~~ Suspicious pharmacy orders are red flags for, if not direct evidence of, diversion.

497. ~~523.~~ Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the Retail Pharmacy Defendants themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

498. ~~524.~~ According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

499. ~~525.~~ Despite their legal obligations as registrants under the CSA and Kentucky CSA, the Retail Pharmacy Defendants allowed widespread diversion to occur—and they did so knowingly.

500. ~~526.~~ Performance metrics and prescription quotas adopted by the Retail Pharmacy Defendants for their retail stores contributed to their failure. Under CVS’s Metrics System, for example, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many

prescriptions that pharmacist fills within a year. The resulting focus on quantity, versus quality,

led to a steep and unfettered increase in the flow of opioids throughout the Commonwealth of Kentucky. Yet, the Retail Pharmacy Defendants' policies remained in place even as the opioid epidemic flourished.

501. ~~527.~~ Upon information and belief, this problem was compounded by the Retail Pharmacy Defendants' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

502. ~~528.~~ Upon information and belief, the Retail Pharmacy Defendants also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

503. ~~529.~~ Upon information and belief, the Retail Pharmacy Defendants failed to analyze:

- ☐ the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community;
- ☐ the increase in opioid sales relative to past years;
- ☐ the number of opioid prescriptions filled relative to other drugs; and
- ☐ the increase in annual opioid sales relative to the increase in annual sales of other drugs.

504. ~~530.~~ Upon information and belief, the Retail Pharmacy Defendants also failed to conduct adequate internal or external audits of their opioid sales to identify patterns

regarding

prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

505. ~~531.~~ Upon information and belief, the Retail Pharmacy Defendants also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

506. ~~532.~~ The Retail Pharmacy Defendants were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas clearly and facially inappropriate. Yet, the Retail Pharmacy Defendants did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

2. Multiple Enforcement Actions against the Retail Pharmacy Defendants Confirms their Compliance Failures.

507. ~~533.~~ The Retail Pharmacy Defendants have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the Retail Pharmacy Defendants have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the Retail Pharmacy Defendants.

a. CVS.

508. ~~534.~~ CVS is one of the largest companies in the world, with annual revenue of more than \$150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. As such, CVS was and remains uniquely positioned to serve as a gatekeeper to step the diversion and abuse of opioids. But, like the other Defendants herein, CVS put its profit goals over its obligations to safeguard the public.

509. ~~535.~~ Notably, CVS has been a repeat offender, having paid fines totaling over \$40 million as the result of a series of investigations by the DEA and the U.S. Department of Justice (“DOJ”).

510. ~~536.~~ CVS’ did not alter its conduct, and instead appears to have treated these fines as the cost of doing business—allowing its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing legal obligations.

511. ~~537.~~ As recently as July 2017, CVS entered into a \$5 million settlement with the U.S. Attorney’s Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances. This fine was preceded by numerous others throughout the country.

512. ~~538.~~ In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.

513. ~~539.~~ In October 2016, CVS paid \$600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.

514. ~~540.~~ In September 2016, CVS entered into a \$795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state’s prescription monitoring program website and review a patient’s prescription history before dispensing certain opioid drugs.

515. ~~541.~~ In June 2016, CVS agreed to pay the DOJ \$3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.

516. ~~542.~~ In August 2015, CVS entered into a \$450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.

517. ~~543.~~ In May 2015, CVS agreed to pay a \$22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."

518. ~~544.~~ In September 2014, CVS agreed to pay \$1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.

519. ~~545.~~ In August 2013, CVS was fined \$350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.

520. ~~546.~~ Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.

b. Walgreens.

521. ~~547.~~ Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than \$118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

522. ~~548.~~ Walgreens has also been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—\$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales.

523. ~~549.~~ The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

524. ~~550.~~ Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the national average.

525. ~~551.~~ They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers not only turned a blind eye but provided pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy.

526. ~~552.~~ In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy

of prescriptions coming from pain clinics, that “if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance,” underscoring Walgreens’ attitude that profit outweighed compliance with the its legal reporting obligations.

527. ~~553.~~ Defendant Walgreens’ settlement with the DEA stemmed from the DEA’s investigation into Walgreens’ distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens’ corporate headquarters pushed to increase the number of oxycodone sales to Walgreens’ Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales.

528. ~~554.~~ In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.

529. ~~555.~~ Walgreens has also settled with a number of state attorneys general, including West Virginia (\$575,000) and Massachusetts (\$200,000). The Massachusetts Attorney General’s Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

530. ~~556.~~ In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients’ drug use patterns and didn’t use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed

to pay \$200,000 and

follow certain procedures for dispensing opioids.

c. Rite Aid.

531. ~~557.~~ With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States, with annual revenue of more than \$21 billion.

532. ~~558.~~ In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined \$5 million in civil penalties for its violations of the CSA.

533. ~~559.~~ The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of federal law—Kentucky similarly requires reporting of employee or other theft of opioids.

534. ~~560.~~ Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from Retail Pharmacy Defendants. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

535. ~~561.~~ The litany of state and federal actions against the Retail Pharmacy Defendants demonstrate that they routinely, and as a matter of standard operation procedure, violate their legal obligations under the CSA and Kentucky laws and regulations that govern the distribution and dispensing of prescription opioids.

536. ~~562.~~ Throughout the Commonwealth of Kentucky, the Retail Pharmacy Defendants

were or should have been aware of numerous red flags of potential suspicious activity and diversion.

537. ~~563.~~ On information and belief, the Retail Pharmacy Defendants knew or reasonably should have known about the disproportionate flow of opioids into Kentucky and the operation of “pill mills” that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

538. ~~564.~~ On information and belief, the Retail Pharmacy Defendants knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

539. ~~565.~~ On information and belief, because of (among other sources of information) regulatory and other actions taken against the Retail Pharmacy Defendants directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the Retail Pharmacy Defendants were well aware that their distribution and dispensing activities fell far short of legal requirements.

540. ~~566.~~ The Retail Pharmacy Defendants’ actions—or inaction and omissions—in failing to effectively prevent the diversion and abuse of opioids, and in failing to monitor, report, and prevent suspicious opioid orders contributed significantly to the opioid epidemic throughout the Commonwealth of Kentucky and for which the Plaintiffs seek relief herein.

G. The Opioid (“Marketing”) Defendants Colluded and Conspired in the Marketing, Promotion, Distribution, Sale, and Dispensing of Opioids.

1. The Opioid Conspiracy’s Purpose—Increased Sales & Profit.

563. ~~567.~~ The Opioid (“Marketing”) Defendants are defined to include the Purdue Entities, Rhodes Entities, Sackler Defendants, Endo Entities, Johnson & Johnson Entities, Mallinckrodt Entities, and Teva Entities.

564. ~~568.~~ The Opioid (“Marketing”) Defendants initial collusion began with the development of a stronger and more additive poppy strain—the key precursor to creating opioid drugs.

565. ~~569.~~ Again, as already noted, to increase demand, market share, and ultimately the Opioid (“Marketing”) Defendants, the Johnson & Johnson Entities began a project to develop a *high thebaine*⁸ poppy—subsequently named the *Norman Poppy*. The Johnson & Johnson Entities described the *Norman Poppy* as a *transformational* technology that would drive the significant growth of the oxycodone market.

566. ~~570.~~ With specifically enhanced *Norman Poppy* product, the Opioid (“Marketing”) Defendants had their opioid API necessary to produce mass quantities of highly addictive opioid drugs—e.g. oxycodone, hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone.

567. ~~571.~~ The Johnson & Johnson Entities’ efforts resulted in their “pain management franchise” becoming the number one (#1) supplier of narcotic API’s in the U.S. By effectively cornering the market with its API production—using opium poppy plant production, extraction, and importation—the Johnson & Johnson Entities were uniquely positioned to provide U.S.

⁸ Thebaine, also known as codeine methyl enol ether, is an opiate alkaloid.

opioid manufacturers with what it deemed “Security of Supply” and “Direct Access to Narcotic Raw Material - From Our Fields to Your Formulations.” Using its franchise, the Johnson & Johnson Entities supplied the necessary opioid component—oxycodone API—to U.S. opioid manufacturers.

568. ~~572.~~ With the knowledge of that their opioid products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the Opioid (“Marketing”) Defendants formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain—the “Opioid Conspiracy.”

569. ~~573.~~ In order to unlawfully increase the demand for opioids, the Opioid (“Marketing”) Defendants formed an association-in-fact enterprise with the “Front Groups” and KOLs described above.

570. ~~574.~~ Through their personal relationships, the Manufacturer (“Marketing”) Defendants had the opportunity to form and take actions in furtherance of their common purpose and objective—to significantly increase the public consumption of opioids for their collective and individual financial gain.

571. ~~575.~~ The Opioid (“Marketing”) Defendants, through their collective and joint enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including the Plaintiffs, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use.

572. ~~576.~~ The Opioid Conspiracy’s misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be

effectively managed;

(3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the Opioid (“Marketing”) Defendants named “pseudo addiction”; (4) that withdrawal is easily managed; (5) that increased dosing present no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and

(9) that abuse-deterrent formulations provide a solution to opioid abuse.

573. ~~577.~~ The Opioid Conspiracy devised, implemented and conducted by the Opioid (“Marketing”) Defendants was a common course of conduct designed to ensure that the Opioid (“Marketing”) Defendants unlawfully increased their sales and profits through active concealment and public misrepresentations about the addictive nature and effective use of opioids—including their own branded opioids.

574. ~~578.~~ The Opioid (“Marketing”) Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetuated their Opioid Conspiracy, including through the unbranded promotion and marketing network as described above.

575. ~~579.~~ There was regular communication between the Opioid (“Marketing”) Defendants, Front Groups and KOLs, in which information was shared, misrepresentations were coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail in which the Opioid (“Marketing”) Defendants, Front Groups, and KOLs share information regarding overcoming public objections and resistance to the long-term use of opioids for chronic pain.

576. ~~580.~~ The Opioid (“Marketing”) Defendants, Front Groups and KOLs functioned

as a continuing and cooperate enterprise for the express purpose of implementing the Opioid

Conspiracy's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

577. ~~581.~~ At all relevant times, the Front Groups were aware of the Opioid (“Marketing”) Defendants’ conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same Opioid Conspiracy scheme, to the detriment of the public and end-users, prescribers, and the Plaintiffs.

578. ~~582.~~ At all relevant times, the KOLs were aware of the Opioid (“Marketing”) Defendants’ conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct.

579. ~~583.~~ The Opioid (“Marketing”) Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The Opioid (“Marketing”) Defendants’ financial support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the Opioid (“Marketing”) Defendants by advancing their marketing goals.

580. ~~584.~~ The KOLs also knew, but did not disclose, that the other KOLS and Front Groups were engaged in the same Opioid Conspiracy scheme, to the detriment of the public and end- users, prescribers, and the Plaintiffs.

581. ~~585.~~ As public scrutiny and media coverage focused on how opioids ravaged communities in the Commonwealth of Kentucky and throughout the United States, the Front Groups and KOLS did not challenge the Opioid (“Marketing”) Defendants’ misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Conspiracy scheme, nor disclose publicly that the risks of using opioids for chronic pain outweighed their

benefits and were not supported by medically acceptable evidence.

582. ~~586.~~ The Opioid (“Marketing”) Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Conspiracy scheme—to dramatically increase the use of opioids. As described herein, the Opioid (“Marketing”) Defendants’ conduct in furtherance of the common purpose of the Opioid Conspiracy involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability.

583. ~~587.~~ In addition to disseminating misrepresentations about the risks and benefits of opioids, the Opioid Marketing Enterprise also furthered its common purpose by criticizing or undermining CDC Guideline. Members of the Opioid Marketing Enterprise criticized or undermined the CDC Guideline, which represented “an important step—and perhaps the first major step from the federal government—toward limiting opioid prescriptions for chronic pain.”

584. ~~588.~~ Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the “CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines.”

585. ~~589.~~ The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating “that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence.”

586. ~~590.~~ The Opioid (“Marketing”) Defendants alone could not have accomplished the purpose of the Opioid Conspiracy without the assistance of the Front Groups and KOLs,

who

were perceived as “neutral” and more “scientific” than the Opioid (“Marketing”) Defendants themselves. Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the Opioid Conspiracy could not have achieved its common purpose—underscoring the Opioid (“Marketing”) Defendants need to both create, manipulate, and control the public messages.

587. ~~591.~~ The impact of the Opioid Conspiracy remains in place—i.e., the opioids continue to be prescribed and used for long-term treatment of chronic pain throughout the Commonwealth of Kentucky and the resulting opioid epidemic continues unabated—injuring the end-users, the public and the Plaintiffs.

588. ~~592.~~ As a result, it is clear that Opioid (“Marketing”) Defendants were each willing participants in the Opioid Conspiracy, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Opioid Conspiracy’s purpose—the significant and exponential increase in the sale of opioids and resulting profits, at the expense of the end-users, the public, and the Plaintiffs.

2. The Opioid Marketing Conspiracy.

589. ~~593.~~ From approximately the late 1990s to the present, each of the Opioid (“Marketing”) Defendants exerted control over the Opioid Conspiracy and participated in the operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

- Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, end-users, and payors;
- Creating and providing a body of deceptive, misleading and

unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

- Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the Opioid (“Marketing”) Defendants’ messages about the use of opioids for chronic pain;
- Providing substantial opportunities for KOLs to participate in research studies on topics the Opioid (“Marketing”) Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
- Paying KOLs to serve as consultants or on the Opioid (“Marketing”) Defendants’ advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;
- Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the Opioid (“Marketing”) Defendants’ messages about the use of opioids for chronic pain;
- Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the Opioid (“Marketing”) Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

- Paying significant amounts of money to the leaders and individuals associated with Front Groups;
- Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;
- Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;
- Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;
- Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;
- Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Marketing Defendants, such as veterans and the elderly, and then funding that distribution;
- Concealing their relationship to and control of Front Groups and KOLs from the Plaintiff and the public at large; and
- Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

590. ~~594.~~ The Opioid Conspiracy had a hierarchical decision-making structure that was headed by the Opioid (“Marketing”) Defendants and corroborated by the KOLs and Front Groups. The Opioid (“Marketing”) Defendants controlled representations made about their opioids, doled out funds to insurance intermediaries, made payments to KOLs, and ensured that representations made by KOLs, Front Groups, and the Opioid (“Marketing”) Defendants’ sales detailers were consistent with the messaging throughout the United States and the Commonwealth of Kentucky. The Front Groups and KOLS in the Opioid Conspiracy were dependent on the Opioid (“Marketing”) Defendants for their financial structure and for career development and promotion opportunities.

591. ~~595.~~ As the behest of the Opioid (“Marketing”) Defendants, the Front Groups also conducted and participated in the conduct of the Opioid Conspiracy, directly or indirectly, in the following ways:

- The Front Groups promised to, and did, make representations regarding opioids and the Opioid (“Marketing”) Defendants’ opioids that were consistent with the Opioid (“Marketing”) Defendants’ marketing messages;
- The Front Groups distributed promotional and other materials which claimed that opioids could be safely used long-term for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;
- The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the Opioid (“Marketing”) Defendants;
- The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- The Front Groups concealed their connections to the KOLs and the Opioid (“Marketing”) Defendants.

592. ~~596.~~ The Opioid (“Marketing”) Defendants’ Front Groups, “with their large numbers and credibility with policymakers and the public—have ‘extensive influence in specific disease areas.’” The larger Front Groups “likely have a substantial effect on policies relevant to their industry sponsors.” “By aligning medical culture with industry goals in this way, many of the groups described in the [Fueling an Epidemic] report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic.”

593. ~~597.~~ At the behest of the Opioid (“Marketing”) Defendants, the KOLs participated in the conduct of the affairs of the Opioid Conspiracy, directly or indirectly, in the

following ways:

- The KOLs promised to, and did, make representations regarding opioids and the As the behest of the Opioid (“Marketing”) Defendants’ opioids that were consistent with the As the behest of the Opioid (“Marketing”) Defendants’ marketing messages;
- The KOLs distributed promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for long-term chronic pain outweighed the risks;
- The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the Opioid (“Marketing”) Defendants;
- The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- The KOLs concealed their connections to the Front Groups and the Opioid (“Marketing”) Defendants, and their sponsorship by the Opioid (“Marketing”) Defendants.

594. ~~598.~~ The scheme devised and implemented by the Opioid (“Marketing”) Defendants amounted to a common course of conduct intended to increase the Opioid (“Marketing”) Defendants’ sales and profits from the distribution, sale, and dispensing of prescription opioids by deceptively encouraging the use of opioids for long-term chronic pain. The Opioid Conspiracy was a continuing course of conduct, and many aspects of it continue through to the present.

3. The Opioid (“Marketing”) Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use.

595. ~~599.~~ As previously noted, the Opioid (“Marketing”) Defendants funded and controlled multiple Front Groups, including APF, AAPM/APS, FSMB, Alliance for Patient Access, USPF, and AGS. The Front Groups, which from a public perspective were falsely

presented as

independent, provided a conduit for the Opioid (“Marketing”) Defendants’ false messages.

596. ~~600.~~ The Opioid (“Marketing”) Defendants clandestinely worked through each of the Front Groups—providing funding, support, and ultimately the precise messaging to be presented to the public.

597. ~~601.~~ Again as previously noted, the Opioid (“Marketing”) Defendants paid KOLs, including Drs. Portenoy and Webster, to spread their false marketing messages, to misrepresent the efficacies and dangers of opioids, and to ultimately sell more of their opioid products.

4. Additional Evidence of the Opioid Conspiracy.

598. ~~602.~~ The Opioid (“Marketing”) Defendants devised and knowingly carried out the illegal Opioid Conspiracy scheme to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the efficacies and dangers associated with using opioids for long-term chronic, non-acute and non-cancer pain.

599. ~~603.~~ The Opioid (“Marketing”) Defendants knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence, which in turn violated Kentucky’s laws which incorporated federal requirements as a statutory and regulatory requirement.

600. ~~604.~~ The Opioid (“Marketing”) Defendants intended that that their common Opioid Conspiracy scheme to deceive prescribers, regulators, end-users, the public, and the Plaintiffs.

601. ~~605.~~ By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for long-term chronic pain to prescribers, regulators, end-users, the public, and the Plaintiffs, the Opioid (“Marketing”) Defendants engaged in a fraudulent and unlawful course of conduct constituting a conspiracy in violation of

Kentucky law.

602. ~~606.~~ The Opioid (“Marketing”) Defendants’ efforts to perpetuate and to accomplish the

goals of their Opioid Conspiracy relied in part on thousands of communications, publications, representations, statements, electronic transmissions, payments, including, inter alia:

- Marketing materials about opioids, and their risks and benefits, which the Opioid (“Marketing”) Defendants sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and KOLs;
- Written representations and telephone calls between the Opioid (“Marketing”) Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- Written representations and telephone calls between the Opioid (“Marketing”) Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- E-mails, telephone and written communications between the Opioid (“Marketing”) Defendants and the Front Groups agreeing to or implementing the Opioid Conspiracy;
- E-mails, telephone and written communications between the Opioid (“Marketing”) Defendants and the KOLs agreeing to or implementing the Opioid Conspiracy;
- Communications between the Opioid (“Marketing”) Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Conspiracy;
- Communications between the Opioid (“Marketing”) Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Conspiracy; and

Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout Plaintiff’s community that fraudulently misrepresented the risks and benefits of using opioids for long-term treatment of chronic pain.

603. ~~607.~~ To achieve the common goal and purpose of the Opioid Conspiracy,

Opioid (“Marketing”) Defendants hid from the prescribers, regulators, end-users, the

public, and

ultimately the Plaintiffs:

- the fraudulent nature of the Opioid (“Marketing”) Defendants’ marketing scheme;
- the fraudulent nature of statements made by the Opioid (“Marketing”) Defendants and by their KOLs, Front Groups and other third parties regarding the safety and efficacy of prescription opioids; and
- the true nature of the relationship between the Opioid (“Marketing”) Defendants, the KOLs, Front Groups, and other third parties participating—at the Opioid (“Marketing”) Defendants’ direction and control—in the false messages and marketing in furtherance of the Opioid Conspiracy.

604. ~~608.~~ The Opioid (“Marketing”) Defendants agreed, with knowledge and intent, to the overall objective of the Opioid Conspiracy, and to actively participate in the common course of conduct necessary to fulfill the objectives of the conspiratorial scheme—thereby committing acts of fraud, deception, and illegal marketing of prescription opioids solely for financial gain with reckless disregard and wholesale indifference to the devastating damage to the end-user, the public, and the Plaintiffs.

605. ~~609.~~ Indeed, for the Opioid (“Marketing”) Defendants fraudulent Opioid Conspiracy to work, each of them had to absolutely cooperate and agree to implement the same fraudulent, deceptive, and illegal tactics. This conclusion is further supported by the fact that the Opioid (“Marketing”) Defendants each financed, supported, and worked to advance the Opioid Conspiracy through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines.

606. ~~610.~~ The Opioid (“Marketing”) Defendants’ conspiratorial actions all had the express purpose of dramatically and exponentially increasing the demand for opioids—thereby creating the very opioid epidemic that now plagues the Commonwealth of Kentucky and that has significantly damaged the end-users, the public, and the Plaintiffs—from which the Opioid

(“Marketing”) Defendants simultaneously generating billion-dollar revenue and profits.

H. The Manufacturer and Distributer (“Opioid Supply”) Defendants Colluded and Conspired in the Marketing, Promotion, Distribution, Sale, and Dispensing of Opioids.

607. ~~611.~~ The Opioid Supply Defendants are defined to include: (i) the Manufacture (“Marketing”) Defendants: Allergan Entities, Endo Entities, Mallinckrodt Entities, Purdue Entities, Rhodes Entities, Sackler Defendants, and Teva Entities; and (ii) the Wholesale Distributor Defendants: Amerisource Bergen Entities, Cardinal Health, and McKesson (collectively, the “Opioid Supply Defendants”).

608. ~~612.~~ Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, a number of opioid defendants resorted to making a public “categorical denial of any criminal behavior or intent.” The denials are not supported by the factual history of the Opioid Supply Defendants’ collaborative actions.

609. ~~613.~~ For more than a decade, the Opioid Supply Defendants collaborated in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding the opioids market.

610. ~~614.~~ Recognizing that dangerous opioids only have a very limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted CSA—incorporated into Kentucky’s laws and regulations.

611. ~~615.~~ Relevant to this lawsuit, the CSA created a closed system of distribution for controlled substances. The CSA imposed a reporting duty that cuts across the Opioid Supply Defendants’ company lines.

612. ~~616.~~ Regulations adopted under the CSA mandates that companies—including the Opioid Supply Defendants—who are entrusted to operate with this system must safeguard the public good and safety. Private companies cannot simply operate as an unregulated “anything goes” profit-maximizing business model. Instead, the CSA requires companies—again, including the Opioid Supply Defendants—to self-regulate not just themselves, but all other companies operating in the manufacture, distribution, sale and dispensing of opioids. The CSA created a mandatory self-reporting mechanism to police the opioid marketplace with the ultimate goal of protecting the end-user and the public.

613. ~~617.~~ Kentucky incorporated the CSA reporting requirements into its own statutory laws and regulations, as well as created additional standards of conduct for opioid manufacturers, distributors, and pharmacies.

614. ~~618.~~ The Opioid Supply Defendants wholly failed to comply with their CSA and, correspondingly, their Kentucky legal obligations. The Opioid Supply Defendants Driven did not fulfill their obligations to protect their end-users, the public, or the Plaintiffs. Instead, driven by greed, the Opioid Supply Defendants the public trust and instead subverted the constraints of the CSA’s closed reporting system to create and conduct their own Opioid Diversion Conspiracy.

615. ~~619.~~ As “registrants” under the CSA, the Opioid Supply Defendants were and remain duty bound to identify and report “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” Critically, their obligations did not end with the products they manufactured or distributed. Thus, when the Opioid Supply Defendants obtained information about the sales and distribution of other companies’ opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity to the DEA.

616. ~~620.~~ In the normal course of business, and absent conspiratorial collusion, competition dictates that the Opioid Supply Defendants would report their opioid competitors for any wrongful or suspicious conduct. This would in turn logically lead to an increasing market share as bad apples are removed. In fact, under the CSA this whistleblower—policing the opioid marketplace—function is a statutory mandate.

617. ~~621.~~ The Opioid Supply Defendants elected not to comply with their legal requirements. Instead, recognizing that increased regulatory attention—even for a competitor—would serve to drive down the entire market—resulting in lower sales and corresponding profits. As such, applying more of a macro, as opposed to a micro, view of the opioid market, the Opioid Supply Defendants elected to collaborate and conspire to do nothing—to engage in silence regardless of their obligations, in this case, under Kentucky law.

618. ~~622.~~ The Opioid Supply Defendants is an enterprise—the Opioid Supply Conspiracy—that began in the mid-90s and developed over the ensuing years to grow into a tightly knit network of multi-billion-dollar companies profiting from branded and generic opioid sales.

619. ~~623.~~ The formation and existence of the Opioid Supply Conspiracy was originally facilitated by direct interactions between the Opioid Supply Defendants. As the Opioid Supply Conspiracy grew, the Opioid Supply Defendants eventually incorporated other resources that allowed them to deepen their relationships and coordinated efforts to avoid federal and state regulatory scrutiny and thereby avoid their regulatory obligations. Some of these additional resources, like the Healthcare Distribution Alliance (together with its predecessors, the “HDA”) were formally organized businesses that existed separate and apart from the Opioid Supply Conspiracy, but were controlled by the Opioid Supply Defendants (through their membership on

the Board of Directors and Executive Committee, and substantial financial contributions) to

achieve the common purpose of Opioid Supply Conspiracy.

620. ~~624.~~ Other resources, like the Pain Care Forum (“PCF”), the New Jersey Pharmaceutical Industry Working Group (“NJPIG”), and the Anti-Diversion Industry Working Group (“ADIWG”), were informal associations created by the Opioid Supply Conspiracy. Specifically, these groups were developed to serve the Opioid Supply Defendants’ mutual interests, allowing them to coordinate their efforts.

621. ~~625.~~ HDA is of particular importance to the Opioid Supply Conspiracy. HDA (through its predecessor entities) was initially formed in 1876 to “remedy the existing evils in the wholesale drug business and enable the merchants to carry on business on a more profitable basis.” It has strayed from its mission and now serves as a powerful tool for the opioid distributor industry to influence the media, the marketplace, state and federal regulators and elections across the country.

622. ~~626.~~ Now headquartered in Arlington, Virginia, HDA represents 36 opioid distribution companies — national, regional and specialty — as well as more than 130 manufacturer and more than 50 service provider/international members, respectively. These members serve more than 200,000 licensed healthcare providers, delivering over 15 million products to these outlets every day. Just as in 1876, HDA’s publicly stated mission has remained the same: to protect patient safety and access to medicines through safe and efficient distribution; to advocate for standards, public policies and business processes that enhance the safety, efficiency and value of the healthcare supply chain; and to create and exchange industry knowledge and best practices.

623. ~~627.~~ HDA is controlled by an Executive Committee which, for all time relevant, included the largest of the Wholesale Distributor Defendants: AmerisourceBergen, Cardinal Health, and McKesson. No decision is made at HDA without the blessing,

permission, and

endorsement of AmerisourceBergen, Cardinal Health, and McKesson.

624. ~~628.~~ The first nexus of communication that lead to the formation of the Opioid Supply Conspiracy began in the mid-90s when the Purdue Entities and the Opioid Supply Defendants began working together on their approach to suspicious order monitoring and the release of Oxycontin.

625. ~~629.~~ As the Purdue Entities wrote, its relationship with the top four wholesalers was very solid. The Purdue Entities' contacts facilitated effortless movement through the Opioid Supply Defendants' organizations. The Purdue Entities explained that with wholesaler friendly policies, the Purdue Entities could expect programs that were friendly and profitable for Purdue.

626. ~~630.~~ Beginning in the early 2000s, the Opioid Supply Defendants' also began working together to protect their interests. Specifically, the Purdue Entities reached out to the Teva Entities to discuss organizing and meeting with other manufacturers, including the Endo Entities and the Johnson & Johnson Entities. The Purdue Entities' suggestion served as the catalyst that led to quarterly meetings in 2004 to discuss public policy issues surrounding pain management, controlled substances, and diversion, abuse and misuse of our products. This group eventually became known as the PCF and its membership included the majority of the Opioid Supply Defendants and the HAD—again, subject to direction by the Opioid Supply Defendants.

627. ~~631.~~ The DEA's increased enforcement in the mid-2000s led to a significant increase in communication between the Opioid Supply Defendants, and in their work with the HDA, PCF, NJPIG and ADIWG, all of which was being conducted to further the goal of unlawfully selling opioids. In 2005 and 2006, the DEA conducted its "Distributor Initiative," which included DEA meetings with registrants, and conferences where DEA explained

suspicious order monitoring requirements, which are part of the larger statutory duty to prevent diversion.

628. ~~632.~~ The DEA also issued three letters (the “Dear Registrant Letters”) as part of the initiative. Finally, in 2007, the DEA issued its first immediate suspension order or “ISO” that suspended AmerisourceBergen’s registration to dispense controlled substances from its Lakeland, Florida distribution center.

629. ~~633.~~ The suspension of AmerisourceBergen’s registration effectively stopped its ability to profit from the distribution of controlled substances during the height of the diversion epidemic in Florida and, more importantly, sent shockwaves through the supply chain industry.

630. ~~634.~~ As documents produced from the HDA indicate, the supply chain industry was concerned about “the intensity and impact of the Drug Enforcement Administration’s recent actions” in 2007. As a result, there was a significant increase in related communications between the Opioid Supply Defendants, in participation in the HDA, PCF, NJPIG, and ADIWG, and interaction between the HDA and PCF. One goal was to “develop a comprehensive DEA strategy.”

631. ~~635.~~ In addition to direct meetings, communications, and interactions of the Opioid Supply Defendants, further collaboration occurred with the HDA, PCF, NJPIG, and ADIWG. These groups were centrally important in the Opioid Supply Defendants’ efforts to counter regulator’s attempts to enforce the suspicious order monitoring provisions of the CSA.

632. ~~636.~~ Through their connections in these groups, the Opioid Supply Defendants managed to avoid their obligations under the closed system designed to protect the citizens. Through their work with the HDA in particular, the Opioid Supply Defendants were able to formulate a comprehensive and joint regulatory strategy—part of the Opioid Supply Conspiracy—in response to the suspension of AmerisourceBergen’s registration

and the subsequent suspensions of the McKesson's and Cardinal Health's registrations.

633. ~~637.~~ The Opioid Supply Conspiracy included scheduling meetings with regulators so that HDA's members could argue they were taking action to combat opioid diversion. These meetings led to the recommendation from Cardinal Health that the HDA should develop a set of Industry Compliance Guidelines ("ICGs") for complying with the suspicious order monitoring obligations under the CSA.

634. ~~638.~~ The ICGs are important. First, the HDA worked extremely closely with its members to draft the ICGs, including obtaining copies of its members' suspicious order monitoring policies and procedures, and interviewing members' employees about the members' practices. Eventually, the ICGs were ratified by the Executive Committee of the HDA reflecting an agreement among at least the Opioid Supply Defendants to a course of conduct that should have been utilized as a basis for complying with the CSA that was achieved by reviewing and sharing suspicious order monitoring policies and procedures.

635. ~~639.~~ The HDA also worked extremely closely with regulators, including receiving detailed comments and suggestions about what must be included in the ICGs. As such, HDA and the Opioid Supply Defendants were aware of very specific guidance from the DEA about what was required to comply with the CSA.

636. ~~640.~~ During the drafting of the ICGs, the HDA represented to the DEA that it would work with HDA members to ensure that they implemented the ICGs as part of the HDA's commitment to protecting patient safety. However, the HDA was on already on notice the Opioid Supply Defendants did not intend to implement the ICGs.

637. ~~641.~~ Finally, the HDA represented to regulators that it would work with other supply chain industry stakeholders like the PCF, and other trade associations' manufacturers and pharmacists, to help their members implement the ICGs. Moreover, the HDA presented to

members of the PCF about the ICGs in order to educate them about the efforts HDA was undertaking in that regard.

638. ~~642.~~ HDA's work on the ICGs is strong evidence of the existence of the Opioid Supply Conspiracy, and the Opioid Supply Defendants willing participating and common purpose.

Notably, the HDA publicly represented that it hoped the "DEA would find the guidelines acceptable as a voluntary 'consent decrees'," but "did not expect these guidelines to result in weakening DEA's enforcement prerogatives." Yet, in private conversations with the Opioid Supply Defendants, HDA admitted that the "Purpose of ICG and DEA Communications" was to "'Head-off' further enforcement or regulatory action."

639. ~~643.~~ Further evidence of the Opioid Supply Conspiracy's common purpose related to the ICGs occurred in 2012 when the ICGs were relied on by the DEA in a regulatory enforcement action against Walgreens. After the HDA learned of this information, the Executive Committee instructed HDA to immediately take the ICGs off of the HDA's website because they were never meant to be used as an industry standard to be used against companies in the pharmaceutical supply chain.

640. ~~644.~~ This action by the HDA is particularly indicative of the common purpose of the Opioid Supply Conspiracy because when the HDA originally presented the ICGs to the DEA and analogized them to a similar situation "where a set of voluntary standard were reviewed by FDA and eventually became a standard practice." But when the HDA pulled the ICGs from the website in 2013 they internally discussed that the "guidelines were never intended to constitute a standard" so "they [were] taken down from the HDMA website, at the direction of the [Government & Public Policy Council]" of the HDA.

641. ~~645.~~ Publicly, in 2008, the Opioid Supply Defendants announced the formulation of

“Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances.” But, privately, the Opioid Supply Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA and corresponding state law mandates. Indeed, despite the issuance of these Industry Compliance Guidelines, which actually acknowledge the Opioid Supply Defendants’ legal duties, the Opioid Supply Defendants did not comply.

642. ~~646.~~ Aside from the ICGs, the Opioid Supply Defendants used the HDA to accomplish other goals of the Opioid Supply Conspiracy. By way of example, the HDA lobbied in favor of issues that undermined DEA and its attempts to enforce the CSA, including engaging in negative attacks on the DEA before the Government Accountability Office. The HDA’s efforts to combat and to undermine the Opioid Supply Defendants’ regulatory obligations have continued unabated.

643. ~~647.~~ The sheer volume of prescription opioids distributed, sold, and dispensed through the collaborative efforts of the Opioid Supply Defendants—in furtherance of the Opioid Supply Conspiracy—is overwhelming and now thoroughly documented.

644. ~~648.~~ There is no reasonable answer or excuse for the Opioid Supply Defendants’ complete failure to stem the flood of opioids in the Commonwealth of Kentucky other than that it was done with intent—to accomplish the goals of the Opioid Supply Conspiracy.

645. ~~649.~~ Given their controlling position, and intimate knowledge of each opioid ultimately dispensed to an end-user, the Opioid Supply Defendants were uniquely and unquestionably best suited to identify each and every suspicious transaction in the Commonwealth of Kentucky. The Opioid Supply Defendants simply elected not to take any action and to instead focus on maintaining and increasing their sales and corresponding profits.

646. ~~650.~~ As described above, at all relevant times, the Opioid Supply Defendants operated as an association-in-fact enterprise formed for the express purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute.

647. ~~651.~~ In support of this common purpose and fraudulent scheme, the Opioid Supply Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, their allowable sales quotas.

648. ~~652.~~ At all relevant times, as described above, the Opioid Supply Defendants exerted control over, conducted and/or participated in the Opioid Supply Conspiracy by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

649. ~~653.~~ The Opioid Supply Defendants disseminated false and misleading statements to state and federal regulators claiming that:

- the quotas for prescription opioids should be increased;
- they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;
- they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;
- they were complying with their obligation to notify the DEA of any

suspicious orders or diversion of their prescription opioids; and

- they did not have the capability to identify suspicious orders of controlled substances.

650. ~~654.~~ During the relevant time period, each Opioid Supply Defendants exerted control over and participated in the operation and management of the Opioid Supply conspiracy directly or indirectly, in the following ways:

- the Opioid Supply Defendants were required to each obtain a license from the Kentucky Board of Pharmacy;
- the Opioid Supply Defendants, contrary to Kentucky law, failed to take necessary action to prevent the diversion of dangerously addictive prescription opioids;
- the Opioid Supply Defendants, contrary to Kentucky law, and in dereliction of non-delegable duties, distributed and sold opioids to their retail pharmacy customers without regard to the frequency, quantity, or any other serious red flags;
- the Opioid Supply Defendants misrepresented their compliance with their Kentucky legal obligations, making false assurances that their distribution complied with Kentucky law, when they were instead distributing and selling as many opioids as possible;
- the Opioid Supply Defendants violated their legal duties to guard against diversion of the opioids for illicit purposes, disregarding regulatory warnings;
- the Opioid Supply Defendants refused to abide by the terms of regulatory enforcement actions and settlements, and instead continued to violate their statutory and regulatory obligations;
- the Opioid Supply Defendants did not monitor, detect, investigate, refuse and report suspicious orders to the Kentucky Board of Pharmacy; and
- the Opioid Supply Defendants intentionally sold the opioids unlawfully, purely for profit and without regard to the resulting and growing opioid epidemic, notwithstanding their knowledge that substantial and irreversible harm would occur to the end-user and the public.

651. ~~655.~~ The Opioid Supply Defendants did not undertake the practices described herein in

isolation, but as part of a common scheme—the Opioid Supply Conspiracy.

652. ~~656.~~ The Opioid Supply Defendants’ collaborative and organized actions encompassed a litany of unlawful activities, each conducted with advancing the Opioid Supply Conspiracy’s common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous opioids.

653. ~~657.~~ The Opioid Supply Defendants’ actions had the same or similar detrimental effects on prescribers, end-users, the public and the Plaintiffs. Again, the Opioid Supply Defendants’ actions were not separate and distinct, but rather were taken in furtherance of the Opioid Supply Conspiracy.

654. ~~658.~~ Despite being repeatedly warned, fined, and found to be in violation of applicable law and regulations, the Opioid Supply Defendants’ wrongful conduct and furtherance of their Opioid Supply Conspiracy continued unabated and undeterred.

655. ~~659.~~ The Opioid Supply Defendants elected to put their own financial interests—the billions of dollars in profits they collected from dumping opioids into the Commonwealth of Kentucky—over their legal obligations to protect the public.

I. The State Governmental Defendants failed to fulfill their statutory obligations to police and regulate the manufacture, marketing, distribution, sale and dispensing of opioids.

656. ~~660.~~ KRS 218A and KRS 315 provide a reticulated and detailed legislative mandate for the monitoring, control and regulation of the manufacture, marketing, distribution, sale and dispensing of opioids—controlled substances—within and throughout the Commonwealth.

657. ~~661.~~ As evidenced by the facts herein, by the now publicly available data, it is clear the State Governmental Defendants failed, and continue to fail, to perform their statutory

duties.

CLASS ALLEGATIONS

658. ~~662.~~ The Plaintiffs seek to represent the following class of Kentucky ~~counties~~ Home Rule cities:

All Kentucky ~~Counties (Fiscal Courts)~~ Home Rule cities,
with populations in excess of 4,000 and *excluding* those
that have filed, and have pending, a civil action in the
National Prescription Opiate Litigation MDL 2804.

659. ~~663.~~ The Plaintiffs and all others similarly situated are entitled to have this
case maintained as a class action pursuant to Kentucky Rules of Civil Procedure.

660. ~~664.~~ The Plaintiff Class is so numerous that joinder of all persons is impracticable
and inefficient. The Plaintiff Class exceeds sixty (60) ~~Counties~~ Home Rule cities but is less than
one hundred (100).

661. ~~665.~~ There are common issues of law and fact applicable to the Plaintiff Class’
claims and Defendants’ individual and collective liability thereunder. The same facts, the same
Kentucky laws and regulations, and the same issues are at issue—concerning the Defendants
individual and collective manufacture, marketing, distribution, sale and dispensing of opioids
throughout the Commonwealth.

662. ~~666.~~ Resolution of the common question(s) will advance resolution of the Plaintiff
Class’ claims. Defendants’ individual and collective conduct presents common factual questions
that predominate. As such, the Plaintiff Class is necessarily bound together by the common
factual questions relating to whether the Defendants’ individual and collective conduct violated
Kentucky law.

663. ~~667.~~ The Plaintiff Class’ claims are typical. Each putative class member
experienced the same injuries and corresponding damages as the direct and consequential result
of the Defendants individual and collective manufacture, marketing, distribution, sale and
dispensing of opioids throughout the Commonwealth of Kentucky. The Plaintiff Class’ claims

are subject to

the *same facts, law, and defenses*.

664. ~~668.~~ The Plaintiff Class' interests are directly aligned amongst themselves and, as such, they will fairly and adequately represent and protect the interests of the Class members. Further, the Plaintiff Class have retained counsel experienced in the prosecution of class action litigation who will adequately represent the interests of the Plaintiff Class and its members. The Plaintiff Class further are unaware of any conflicts of interests between the Plaintiffs and the absent Plaintiff Class members.

665. ~~669.~~ The Plaintiff Class further have, or can acquire, adequate financial resources to assure that the interests of Plaintiff Class members will be protected. Further, the Plaintiff Class representatives are knowledgeable concerning the subject matter of this action and will assist counsel in the prosecution of this litigation.

666. ~~670.~~ The prosecution of the Plaintiff Class' claims on an individual ad hoc basis would create a substantial risk of inconsistent and/or varying legal outcomes that would establish incompatible standards of conduct. Similarly, such an ad hoc litigation process would create a further substantial risk of a single legal outcome that would as a practical matter be dispositive of other Plaintiff Class members thereby substantially prejudicing their respective interests. Class certification would alleviate these issues and provide for an orderly and efficient resolution for all parties and the Court.

667. ~~671.~~ The prosecution of the Plaintiff Class' claims on an individual ad hoc basis is inappropriate where the Defendants have acted, or in this case refused to act, in such a manner that final injunctive relief is both necessary and required. Similarly, ad hoc litigation is inappropriate where declaratory relief is warranted to a large number of affected persons—the Plaintiff Class. Defendants individual and collective improper actions in the manufacture,

marketing, distribution, sale and dispensing of opioids throughout the Commonwealth of Kentucky warrants and supports relief to the Plaintiff Class—injunctive and declaratory—to remedy the harm and to halt the ongoing harm.

668. ~~672.~~ Finally, the Plaintiff Class’ claims present common questions of law and fact that predominates over all alleged questions affecting individual class members. The same facts and the same Kentucky laws and regulations will dictate the extent and the scope of the Defendants’ individual and collective liability to the Plaintiff Class—thus making the procedural class action mechanism the most fair and, more importantly, efficient means for timely and expeditiously resolving the Plaintiff Class’ claims.

669. ~~673.~~ Given the Plaintiff Class is limited to Kentucky ~~Counties~~ Home Rule cities, and there is little interest in absent class members pursuing separate individual actions—hence the definition carve-out for the ~~Counties~~ Home Rule cities that previously elected to seek relief under federal law in federal court—the class action procedural mechanism is appropriate and a superior means of resolution. That the Plaintiff Class is comprised of governmental entities, the resolution of their claims would occur in this Court regardless thereby satisfying any forum concerns, as well as alleviating any case management issue.

CLAIMS FOR RELIEF

A. Public Nuisance (All Defendants, excl. State Governmental Defendants).

670. ~~674.~~ The Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

671. ~~675.~~ Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable and substantial interference with a right common to the general public, which is the proximate cause of, and/or substantial factor leading to, Plaintiff’s injury.

~~676.~~ Kentucky has declared that “[t]he regulation of controlled substances in this Commonwealth is important and necessary for the preservation of public safety and public health.” Kentucky has further declared “effective control and regulation” of all “persons who are required to obtain a license, certificate, or permit from the Board of Pharmacy, whether located in or outside the Commonwealth, that distribute, manufacture, or sell drugs within the Commonwealth” is necessary in order to “promote, preserve, and protect public health, safety, and welfare.” The Kentucky Board of Pharmacy regulations state that “[a] wholesale distributor shall not . . . operate in a manner that endangers the public health.”

672. ~~677.~~ By causing dangerously addictive drugs to flood the community, and to be diverted for illicit purposes, in contravention of Kentucky law, each Defendant has injuriously affected rights common to the general public, specifically including the rights of the Plaintiffs to public health, public safety, public peace, public comfort, and public convenience. The public nuisance caused by Defendants’ diversion of dangerous drugs has caused substantial annoyance, inconvenience, and injury to the public.

673. ~~678.~~ By selling dangerously addictive opioid drugs diverted from a legitimate medical, scientific, or industrial purpose, Defendants have committed a course of conduct that injuriously affects the safety, health, and morals of the people throughout the Commonwealth of Kentucky.

674. ~~679.~~ By failing to create, maintain, and enforce a closed system that guards against diversion of dangerously addictive drugs for illicit purposes, Defendants injuriously affected public rights, including the right to public health, public safety, public peace, and public comfort of the people throughout the Commonwealth of Kentucky.

675. ~~680.~~ Defendants’ collective and individual wrongful and illegal actions have created a public nuisance. Each Defendant is liable for public nuisance because its conduct at issue has

caused an unreasonable interference with a right common to the people throughout the Commonwealth of Kentucky.

676. ~~681.~~ The Defendants have intentionally and/or unlawfully created an absolute nuisance.

677. ~~682.~~ The people throughout the Commonwealth of Kentucky have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare and safety, and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

678. ~~683.~~ Defendants intentionally, unlawfully, and recklessly manufactured, marketed, distributed, sold, and dispensed opioids that Defendants knew, or reasonably should have known, would be diverted, causing widespread distribution of prescription opioids the people throughout the Commonwealth of Kentucky, resulting in addiction and abuse, an elevated level of crime, death and injuries, a higher level of fear, discomfort and inconvenience, and direct costs to Plaintiffs.

679. ~~684.~~ Defendants have unlawfully and/or intentionally caused and permitted dangerous drugs under their control to be diverted such as to injure the people throughout the Commonwealth of Kentucky.

680. ~~685.~~ Defendants have unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls against diversion. Such conduct was illegal. Defendants' failures to create, maintain, and enforce effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

681. ~~686.~~ Defendants have caused a significant and unreasonable interference with the

public health, safety, welfare, peace, comfort and convenience, and ability to be free from disturbance and reasonable apprehension of danger to person or property.

682. ~~687.~~ Defendants' conduct—in illegally distributing and selling prescription opioids, or causing such opioids to be distributed and sold, where Defendants knew, or reasonably should have known, such opioids would be diverted and possessed and/or used illegally throughout the Commonwealth of Kentucky—is of a continuing and ongoing nature.

683. ~~688.~~ A violation of any rule or law controlling the distribution of opioids throughout the Commonwealth of Kentucky is a public nuisance.

684. ~~689.~~ Defendants' distribution of opioids while failing to maintain effective controls against diversion was proscribed by statute and regulation.

685. ~~690.~~ Defendants' ongoing conduct produces an ongoing public nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed throughout the Commonwealth of Kentucky will in turn be diverted, leading to abuse, addiction, crime, and public health costs.

686. ~~691.~~ Because of the continued use and addiction caused by these illegally distributed opioids, the public will continue to fear for its health, safety and welfare, and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

687. ~~692.~~ Defendants knew, or reasonably should have known, that their conduct would have an ongoing detrimental effect upon the public health, safety and welfare, and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

688. ~~693.~~ Defendants knew, or reasonably should have known, that their conduct would cause an unreasonable invasion of the public's right to health, safety and welfare and the public's

ability to be free from disturbance and reasonable apprehension of danger to person and property.

689. ~~694.~~ Defendants were aware, and at a bare minimum certainly should have been aware, of the unreasonable interference that their conduct would cause throughout the Commonwealth of Kentucky. Defendants are in the business of manufacturing, marketing, distributing, selling, and dispensing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous under Kentucky law.

690. ~~695.~~ Defendants' conduct in marketing, distributing, and selling prescription opioids which they knew, or should have known, would likely be diverted for non-legitimate, non- medical use, creates a strong likelihood that these illegal distributions of opioids would cause death and injuries throughout the Commonwealth of Kentucky. Moreover, there would be significant and unreasonable interference with the public's health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

691. ~~696.~~ The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes throughout the Commonwealth of Kentucky not only caused unnecessary deaths and injuries, but also created a palpable climate of fear among residents where opioid diversion, abuse, addiction were prevalent and where diverted opioids tend to be used frequently.

692. ~~697.~~ Defendants' conduct made, and continues to make, it easier for persons to divert prescription opioids throughout the Commonwealth of Kentucky, thereby constituting a dangerous and ongoing threat to the public.

693. ~~698.~~ Defendants' actions were, at the least, a substantial factor in opioids becoming

widely available and widely used for non-medical purposes. Because of Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

694. ~~699.~~ The presence of diverted prescription opioids throughout the Commonwealth of Kentucky, and the consequence of prescription opioids having been diverted, proximately results in and/or substantially contributing to the creation of significant costs to the Plaintiffs to enforce the law, equip its police force and treat the victims of opioid abuse and addiction.

695. ~~700.~~ Stemming the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help to alleviate this problem, save lives, prevent injuries and make the Commonwealth of Kentucky a safer place to live.

696. ~~701.~~ Defendants' conduct is a direct and proximate cause of and/or a substantial contributing factor to opioid addiction and abuse throughout the Commonwealth of Kentucky, the costs borne by Plaintiffs, and a significant and unreasonable interference with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

697. ~~702.~~ Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of the residents of the Commonwealth of Kentucky, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security. Plaintiffs have a clear and ascertainable right to abate any and all such conduct that perpetuates this nuisance.

698. ~~703.~~ Defendants created an absolute public nuisance. Defendants' actions created and expanded the abuse of opioids, which are dangerously addictive, and the ensuing associated

plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create throughout the Commonwealth of Kentucky.

Despite this, Defendants intentionally and/or unlawfully failed to create, maintain, and enforce effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids or caused opioids to be distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt suspicious orders of opioids or caused such orders to be shipped. Defendants intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

699. ~~704.~~ Defendants knew the prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that where Defendants distributed prescription opioids or caused such opioids to be distributed without maintaining effective controls against diversion, including monitoring, reporting, and refusing shipment of suspicious orders, that the opioids would be diverted, and create an opioid abuse nuisance throughout the Commonwealth of Kentucky.

700. ~~705.~~ Defendants' actions also created a qualified nuisance. Defendants acted recklessly, negligently and/or carelessly, in breach of their duties to maintain effective controls against diversion, thereby creating an unreasonable risk of harm.

701. ~~706.~~ Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

702. ~~707.~~ The damages available to the Plaintiffs include, inter alia, recoupment of

governmental costs, flowing from an ongoing and persistent public nuisance which the government seeks to abate. Defendants' conduct is ongoing and persistent, and the Plaintiffs seek all damages flowing from Defendants' conduct. The Plaintiffs further seeks to abate the nuisance and harm created by Defendants' conduct.

703. ~~708.~~ As a direct result of Defendants' conduct, the Plaintiffs have suffered actual injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services. The Plaintiffs therefore seek recovery for this harm.

704. ~~709.~~ The Plaintiffs have sustained specific and special injuries because their damages include, inter alia, health services, law enforcement expenditures, and costs related to opioid addiction treatment and overdose prevention.

705. ~~710.~~ The Plaintiffs further seek to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and interference with a right common to the public.

706. ~~711.~~ The Plaintiffs seek all legal and equitable relief as allowed by Kentucky law, including inter alia, abatement, compensatory damages, disgorgement, and punitive damages from the Defendants for the creation of a public nuisance, attorneys' fees and costs, and pre- and post-judgment interest.

707. ~~712.~~ Defendants' intentional and unlawful actions, and omissions and unreasonable interference with a right common to the public, are of a continuing nature—thereby justifying the Plaintiffs seeking and obtaining declaratory and injunctive relief.

708. ~~713.~~ Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused throughout the Commonwealth of

Kentucky. Defendants are in the business of manufacturing or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because, inter alia, these drugs are defined under Kentucky law as substances posing a high potential for abuse and severe addiction. Defendants created an absolute public nuisance. Defendants' actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

709. ~~714.~~ The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused and continues to cause significant harm to the ~~community~~ Plaintiffs' cities, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gate-keeping and diversion prevention duties, and the Manufacturer Defendants' fraudulent marketing activities, have caused harm to the ~~entire community~~ Plaintiffs' cities that includes, but is not limited to, the following:

- The high rates of use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.
- Children have fallen victim to the opioid epidemic. Easy access to prescription opioids made opioids a recreational drug of choice among teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.
- Members of the public who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.
- The opioid epidemic has increased health care costs, including the cost of obtaining insurance coverage.
- The Plaintiffs have lost the value of productive and healthy employees.

Defendants' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.

- Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. More prescription opioids sold by Defendants led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.
- Addiction rates have dramatically increased, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.
- The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement.
- The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement, and financial resources of the Plaintiffs.
- Defendants' interference with the comfortable enjoyment of life throughout the Commonwealth of Kentucky is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

710. ~~715.~~ The Plaintiffs have sustained specific and special injuries as described in this Complaint and should be permitted to recover relief for their damages—direct, incidental, and consequential pecuniary—resulting from and relating to Defendants' creation of a public nuisance.

711. ~~716.~~ Therefore, the Plaintiffs seek all legal and equitable relief as allowed by law, including injunctive and declaratory relief, restitution, disgorgement, compensatory and punitive damages, and all damages allowed by Kentucky law to be paid by the Defendants, as well as their attorneys' fees and costs, and pre- and post-judgment interest.

B. Negligence (All Defendants, excl. State Governmental Defendants).

712. ~~717.~~ Plaintiffs re-allege all paragraphs of this Complaint as if set forth fully herein. ~~718.~~714. In Kentucky, a recovery for negligence requires establishment of the elements of

duty, breach of duty, causation, and damages.⁹ Duty is a fluid and elusive concept, and the court’s decision regarding the existence of a duty is described as a, “Policy determination.” Kentucky law has adopted a “universal duty of care,” which requires every person to exercise ordinary care in his activities to prevent foreseeable injury.¹⁰

715. ~~719.~~ The applicable statutes and administrative regulations, as previously referenced herein, impose a duty on each Defendant—manufacturer, distributor, and pharmacy—to maintain, report data, and take affirmative action to prevent the abuse and diversion of opioids. Defendants’ respective obligations exist both as a matter of common law, as well as statutory. *See infra*.

716. ~~720.~~ Given the nature of Defendants’ product—opioids—coupled with known and foreseeable dangers inherent in their use—e.g. addition, overdose, abuse, and diversion—each Defendant undertook and accepted a duty to protect the end-user, the public, and the Plaintiffs from harm.

717. ~~721.~~ Paramount to Defendants’ duty was to monitor the manufacture, distribution sale, and dispensing of opioids throughout the Commonwealth of Kentucky—to ensure the supply of opioids was both reasonable, necessary, and appropriate. Defendants’ monitoring duty, when fulfilled in good faith, would ensure that opioids did not harm the end-user, the public, and the Plaintiffs.

⁹ See *Lewis v. B & R Corp.*, 56 S.W.3d 432, 436-37 (Ky.App.2001); *Mullins v. Commonwealth Life Ins. Co.*, 839 S.W.2d 245, 247 (Ky. 1992).

¹⁰ See *T & M Jewelry, Inc. v. Hicks ex rel. Hicks*, 189 S.W.3d 526 (Ky. 2006).

718. ~~722.~~ Defendants collectively and individually failed to fulfill their respective duty to monitor the manufacture, distribution sale, and dispensing of opioids throughout the Commonwealth of Kentucky.

719. ~~723.~~ As detailed herein, Defendants collectively and individually knowingly and intentionally breached their duty to monitor—to identify, report, and prevent suspicious orders. Instead, Defendants focused on their own financial interests despite the foreseeable harm an uncontrolled and unmonitored flow of opioids into Kentucky would cause.

720. ~~724.~~ The resulting flow of opioids resulted in significant damages to the end users, the public, and ultimately the Plaintiffs. *See supra.*

721. ~~725.~~ Therefore, the Plaintiffs seek all legal and equitable relief as allowed by law, including injunctive and declaratory relief, restitution, disgorgement, compensatory and punitive damages, and all damages allowed by Kentucky law to be paid by each Defendant, as well as their attorneys' fees and costs, and pre- and post-judgment interest.

C. Negligence *Per Se*—Statutory Reporting Violation (All Defendants, excl. State Governmental Defendants).

722. ~~726.~~ Plaintiffs re-allege all paragraphs of this Complaint as if set forth fully herein. ~~727.~~723. Violation of a Kentucky statute gives rise to a private right of action where the injured is within the class of persons the statute intended to be protected. This is true even where the statute is penal in nature and provides no civil remedy and extends to administrative regulations concerning public safety.

724. ~~728.~~ Defendants collectively and individually violated their statutory obligations under KRS 218A Controlled Substances, KRS 315 Pharmacists and Pharmacies, 201 KAR Chapter 2, and 902 KAR Chapter 55, respectively.

725. ~~729.~~ In particular, the Kentucky Board of Pharmacy requires coordination and use of

reported opioid distribution and sale data, and continued demonstration of, “Acceptable operational procedures, including . . . compl[iance] with all DEA regulations.” 201 KAR 2:105 Section (4)(d).

726. ~~730.~~ To promote and to protect the public health and welfare with regards to the use of opioids, the Kentucky Agency for Substance Abuse Policy (KY-ASAP) provides a statewide framework for anti-abuse and anti-diversion practices across the Commonwealth. KY-ASAP is currently being used in many of Kentucky communities as the primary component of a comprehensive drug education/prevention, treatment, and law enforcement programs.

727. ~~731.~~ Defendants, whether as a manufacturer, distributor, or pharmacy, each had separate and distinct reporting requirements regarding dispensing and ordering of opioids— specifically the KY CSA.

728. ~~732.~~ The Kentucky Legislature promulgated the KY CSA to promote the, “Preservation of public safety and public health.” KRS 218A.005(1). The KY CSA requires Defendants—given their involvement with the supply and flow of opioids throughout the Commonwealth of Kentucky—to record all incidences of diversion of controlled substances, including opioids and forward the record to the Cabinet for Health and Family Services. *See e.g.* KRS 218A.200; KRS 218A.170; 902 KAR 55:010.

729. ~~733.~~ The KY CSA further requires that Defendants create, maintain, and adhere to policies and procedures that protect against public health crisis, such as the Opioid Epidemic. This obligation includes ensuring that opioid prescriptions are provided for legitimate medical needs and not likely to be diverted for illicit use.

730. ~~734.~~ The KY CSA creates a broad duty on the part of Defendants to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids. Again,

legislature enacted these laws expressly to protect the public from the dangers and foreseeable harm from dangerous opioids. *See* KRS 218A.200 (record keeping); KRS 218A.160(1)(a) (repealed); 218A.170; 902 KAR. 55:010 Section 4(2)(b); 201 KAR 2:105 Section 2(4)(d)).

731. ~~735.~~ Defendants had a significant legal duty—a mandatory obligation and trust to protect the public—from the harm and dangers known to opioids, including abuse and diversion. Defendants were required to create, maintain, and enforce policies and procedures to identify—to flag—problematic opioid orders and patterns. Defendants were further required to report these suspicious orders—a statutory duty.

732. ~~736.~~ As discussed in detail herein, the Defendants collectively and individually failed to fulfill their mandatory obligations under Kentucky law. Their respective failure constitutes prima facie evidence of negligence per se for which the Plaintiffs are entitled to seek relief for the corresponding damages and harm caused by each Defendant.

733. ~~737.~~ Therefore, the Plaintiffs seek all legal and equitable relief as allowed by law, including injunctive and declaratory relief, restitution, disgorgement, compensatory and punitive damages, and all damages allowed by Kentucky law to be paid by each Defendant, as well as their attorneys' fees and costs, and pre- and post-judgment interest.

D. Negligence *Per Se*-- False Advertising Violation (Opioid (“Marketing”) Defendants and Opioid Supply Defendants).

734. ~~738.~~ Plaintiffs re-allege all paragraphs of this Complaint as if set forth fully herein. ~~739.~~735. Again, a violation of a Kentucky statute gives rise to a private right of action

where the injured is within the class of persons the statute intended to be protected. This is true even where the statute is penal in nature and provides no civil remedy and extends to administrative regulations concerning public safety.

736. ~~740.~~ The Opioid (“Marketing”) Defendants and Opioid Supply Defendants,

collectively and individually, violated their statutory obligations under KRS 517.030(1) which expressly prohibits “false advertising.”

A person is guilty of false advertising when, in connection with the promotion of the sale of or to increase the consumption of property or services, he knowingly makes or causes to be made a false or misleading statement in any advertisement addressed to the public or to a substantial number of persons.

737. ~~741.~~ As discussed herein, the Opioid (“Marketing”) Defendants and Opioid Supply Defendants knowingly and willfully promoted the manufacture, distribution, sale and dispensing of opioids throughout the Commonwealth of Kentucky.

738. ~~742.~~ Through multiple marketing channels, the Opioid (“Marketing”) Defendants and Opioid Supply Defendants advertised—both to the public and to large groups—that opioids were not addictive and that opioids were appropriate for long-term treatment of chronic pain. The advertisements were knowingly and intentionally false in violation of KRS 517.030.

739. ~~743.~~ The Opioid (“Marketing”) Defendants and Opioid Supply Defendants actions constitute prima facie evidence of negligence per se for which the Plaintiffs are entitled to seek relief for the corresponding damages and harm caused by each Defendant.

740. ~~744.~~ Therefore, the Plaintiffs seek all legal and equitable relief as allowed by law, including injunctive and declaratory relief, restitution, disgorgement, compensatory and punitive damages, and all damages allowed by Kentucky law to be paid by each Defendant, as well as their attorneys’ fees and costs, and pre- and post-judgment interest.

E. Negligent Misrepresentation (All Defendants, excl. State Governmental Defendants).

~~745.~~741. Plaintiffs re-allege all paragraphs of this Complaint as if set forth fully herein. ~~746.~~742. Kentucky recognizes, and has adopted, Restatement (Second) of Torts § 552 –

Negligent Misrepresentation.¹¹ In relevant part, the tort elements are as follows:

(1) One who, in the course of his business ... or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.

* * * * *

(3) The liability of one who is under a public duty to give the information extends to loss suffered by any of the class of persons for whose benefit the duty is created, in any of the transactions in which it is intended to protect them.

743. ~~747.~~ As discussed in detail herein, the Manufacturer (“Marketing”) Defendants and the Wholesale Distributor Defendants collectively and individually had a duty to supply truthful information concerning opioids—specifically the efficacy and risks associated with long-term use for chronic pain.

744. ~~748.~~ Despite this duty, the Manufacturer (“Marketing”) Defendants and the Wholesale Distributor Defendants collectively and individually knowingly and intentionally provided false information to prescribers, end-users, the public, and the Plaintiffs concerning the use of opioids. ~~749.~~745. The Manufacturer (“Marketing”) Defendants and the Distributor failed to exercise reasonable care in communicating accurate and truthful information concerning opioids—instead, as detailed herein, spreading misinformation and misleading marketing messages for their own respective financial gain.

746. ~~750.~~ As the direct consequence of the Manufacturer (“Marketing”) Defendants’ and the Wholesale Distributor Defendants’ actions, the Plaintiffs have suffered pecuniary

¹¹ See *Presnell Constr. Managers, Inc. v. EH Constr., LLC*, 134 S.W.3d 575 (Ky. 2004).

damages for

which relief is both warranted and necessary.

747. ~~751.~~ Also as discussed in detail herein, all of the Defendants collectively and individually had a public duty—common law and statutory—to monitor the manufacture, distribution, sale, and dispensing of opioids throughout the Commonwealth of Kentucky.

748. ~~752.~~ Despite this duty, all of the Defendants collectively and individually failed to fulfill their respective duties relating to suspicious orders.

749. ~~753.~~ As the direct consequence of all of the Defendants’ actions—or inactions—the Plaintiffs have suffered damages for which relief is both warranted and necessary.

750. ~~754.~~ Therefore, the Plaintiffs seek all legal and equitable relief as allowed by law, including injunctive and declaratory relief, restitution, disgorgement, compensatory and punitive damages, and all damages allowed by Kentucky law to be paid by each Defendant, as well as their attorneys’ fees and costs, and pre- and post-judgment interest.

F. Civil Conspiracy (Opioid (“Marketing”) Defendants).

751. ~~755.~~ Plaintiffs re-allege all paragraphs of this Complaint as if set forth fully herein. ~~756.~~ 752. Kentucky recognizes the tort of civil conspiracy which it defines as a “corrupt or unlawful combination or agreement between two or more persons to do by concert of action an unlawful act, or to do a lawful act by unlawful means.”¹²

753. ~~757.~~ In order to prevail on a claim of conspiracy, the Plaintiffs need only show an unlawful or corrupt agreement between the Defendants to engage in, by some concerted action,

¹² See *Peoples Bank of Northern Kentucky, Inc. v. Crowe Chizek and Co. LLC*, 277 S.W.3d 255, 261 (Ky.App.2008).

the unlawful act. Concerted action has been taken to mean that the parties undertook some “overt act done pursuant to or in furtherance of conspiracy.”¹³

¹³ See *Davenport’s Adm’x v. Crummies Creek Coal Co.*, 184 S.W.2d 887 (1945).

754. ~~758.~~ As detailed herein, the Opioid (“Marketing”) Defendants engaged in a civil conspiracy to create a public nuisance—demonstrated in large part by their concerted efforts to avoid their reporting obligations for suspicious orders and to violate Kentucky law by disseminating false and misleading information concerning the efficacy and risks of long-term opioid use for chronic pain.

755. ~~759.~~ The Opioid (“Marketing”) Defendants acted with a common understanding and orchestrated plan to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, to create the Plaintiffs’ injuries alleged herein.

756. ~~760.~~ As the direct consequence of all of the Opioid (“Marketing”) Defendants’ concerted actions, the Plaintiffs have suffered damages for which relief is both warranted and necessary.

757. ~~761.~~ Therefore, the Plaintiffs seek all legal and equitable relief as allowed by law, including injunctive and declaratory relief, restitution, disgorgement, compensatory and punitive damages, and all damages allowed by Kentucky law to be paid by each of the Opioid (“Marketing”) Defendants, as well as their attorneys’ fees and costs, and pre- and post-judgment interest.

G. Civil Conspiracy (Opioid Supply Defendants).

758. ~~762.~~ Plaintiffs re-allege all paragraphs of this Complaint as if set forth fully herein.

~~763.~~759. As detailed herein, the Opioid Supply Defendants engaged in a civil conspiracy to create a public nuisance—largely in part by their concerted efforts to avoid their reporting obligations for suspicious orders and to violate Kentucky law by using false and misleading information concerning the efficacy and risks of long-term opioid use for chronic pain.

760. ~~764.~~ The Opioid Supply Defendants acted with a common understanding and

orchestrated plan to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, to create the Plaintiffs' injuries alleged herein.

761. ~~765.~~ As the direct consequence of all of the Opioid Supply Defendants' concerted actions, the Plaintiffs have suffered damages for which relief is both warranted and necessary.

762. ~~766.~~ Therefore, the Plaintiffs seek all legal and equitable relief as allowed by law, including injunctive and declaratory relief, restitution, disgorgement, compensatory and punitive damages, and all damages allowed by Kentucky law to be paid by each of the Opioid Supply Defendants, as well as their attorneys' fees and costs, and pre- and post-judgment interest.

H. Consumer Protection (All Defendants, excl. State Governmental Defendants).

763. ~~767.~~ Plaintiffs re-allege all paragraphs of this Complaint as if set forth fully herein. ~~768.~~764. Kentucky's Legislature enacted the Consumer Protection Act to protect the public against predatory or inappropriate actions from those businesses—e.g. Defendants—engaged in selling their products within the Commonwealth.

The General Assembly finds that the public health, welfare and interest require a strong and effective consumer protection program to protect the public interest and the well-being of both the consumer public and the ethical sellers of goods and services...¹⁴

765. ~~769.~~ The primary focal point of Kentucky's Consumer Protection Act was to prevent abuses in the sales process. To that end, Kentucky's Legislature defined what constitutes an unlawful act what would violate the Act and be contrary to the public good.

Unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared

¹⁴ See KRS 367.120(1).
See KRS 367.170(1).

unlawful.¹⁵

See KRS 367.170(1).

766. ~~770.~~ Moreover, to underscore the importance of businesses not engaging in any unlawful act, Kentucky's Legislature further defined an *unfair* to mean *unconscionable*.¹⁶

767. ~~771.~~ As discussed herein in detail, Defendants collectively and individually committed unfair, false, misleading, and/or deceptive acts with regard to the manufacture, distribution, sale, and dispensing of opioids throughout the Commonwealth of Kentucky.

768. ~~772.~~ Pursuant to KRS 367.200, "[t]he court may make such additional orders or judgments as may be necessary to restore to any person in interest any moneys or property, real or personal, which may have been paid out as a result of any practice declared to be unlawful by KRS 367.130 to 367.300." The Plaintiffs are a "person" for purposes of this statute.

769. ~~773.~~ The unfair, false, misleading, and/or deceptive acts committed by Defendants collectively and individually constitute a breach of the duties enumerated under Kentucky law, including but not limited to the Consumer Protection Act.

770. ~~774.~~ As the direct consequent of Defendants' collective and individual actions, the end-users, the public, and ultimately the Plaintiffs were damaged. By way of example, inter alia,

- The resulting high rates of opioid use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.
- Children have fallen victim to the opioid epidemic, with infants born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts (e.g. NAS babies).
- Residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.
- The opioid epidemic has increased health care costs, including the cost

See KRS 367.170(2).

of obtaining insurance coverage.

See KRS 367.170(2).

- Employers have lost the value of productive and healthy employees.
- Diversion of opioids has led to increased criminal activity and fueled a new wave of addiction, abuse, and injury.

771. ~~775.~~ Therefore, the Plaintiffs seek all legal and equitable relief as allowed by law, including injunctive and declaratory relief, restitution, disgorgement, compensatory and punitive damages, and all damages allowed by Kentucky law to be paid by each Defendant, as well as their attorneys' fees and costs, and pre- and post-judgment interest.

I. Fraud by Omission (All Defendants, excl. State Governmental Defendants).

772. ~~776.~~ Plaintiffs re-allege all paragraphs of this Complaint as if set forth fully herein. ~~777-773.~~ Under Kentucky law, fraud by omission includes the following four elements:

- a duty to disclose a fact or facts;
- a failure to disclose such fact;
- the failure to disclose induced action; and
- resulting damages from the failure to disclose.¹⁷

774. ~~778.~~ As previously discussed in detail herein, each Defendant was under a legal duty to investigate, to flag, and to report suspicious orders. Defendants were required by Kentucky law to disclose or report orders of unusual size, orders deviating substantially from a normal pattern, or orders of unusual frequency.

775. ~~779.~~ Also as previously discussed herein, Defendants knowingly failed to comply with their legal obligations in Kentucky—both the CSA and KY's CSA.

776. ~~780.~~ Contrary to their obligations under Kentucky law, Defendants collectively and individually marketed, distributed, sold, and dispensed opioids throughout the

¹⁷ See *Rivermont Inn, Inc. v. Bass Hotels & Resorts, Inc.*, 113 S.W.3d 636, 641 (Ky.App.2003).

Kentucky without adequate policies and procedures to prevent the abuse and/or the diversion of opioids—resulting in the opioid epidemic.

777. ~~781.~~ Despite having full access to opioid sales data information—e.g. the opioid type, dosage, quantity, date, purchaser, and prescriber—the Defendants collectively and individually intentionally and/or recklessly failed to disclose suspicious orders and failed to confirm the order was for a legitimate medical purpose.

778. ~~782.~~ As the direct consequent of Defendants’ collective and individual actions, the end-users, the public, and ultimately the Plaintiffs were damaged. By way of example, inter alia,

- The resulting high rates of opioid use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.
- Children have fallen victim to the opioid epidemic, with infants born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts (e.g. NAS babies).
- Residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.
- The opioid epidemic has increased health care costs, including the cost of obtaining insurance coverage.
- Employers have lost the value of productive and healthy employees.
- Diversion of opioids has led to increased criminal activity and fueled a new wave of addiction, abuse, and injury.

779. ~~783.~~ Therefore, the Plaintiffs seek all legal and equitable relief as allowed by law, including injunctive and declaratory relief, restitution, disgorgement, compensatory and punitive damages, and all damages allowed by Kentucky law to be paid by each Defendant, as well as their attorneys’ fees and costs, and pre- and post-judgment interest.

J. Unjust Enrichment (All Defendants, excl. State Governmental Defendants).

780. ~~784.~~ Plaintiffs re-allege all paragraphs of this Complaint as if set forth fully herein. ~~785.~~ 781. Defendants collectively and individually created and maintained an artificial

market for opioids within the Commonwealth of Kentucky that only served the purpose of spreading addiction while at the same time providing each Defendant with a significant and growing stream of revenue.

782. ~~786.~~ Defendants collectively and individually received significant financial rewards from the improper distribution, sale, and dispensing of opioids across the Commonwealth of Kentucky.

783. ~~787.~~ Defendants collectively and individually failed to take the necessary and regulatory required steps to stem the flow of opioids and to abate the foreseeable damages to the end-users, the public, and the Plaintiffs.

784. ~~788.~~ Defendants collectively and individually profited at the direct expense of the end- users, the public, and the Plaintiffs. The profits were directly tied to the funds collected from end-users—either directly paid or paid on their behalf from 3rd parties (e.g. insurers).

785. ~~789.~~ Defendants collectively and individually have been, and continue to be, unjustly enriched at the expense of the end-users, the public, and ultimately the Plaintiffs—for which no equitable benefit has been received in exchange. To the contrary, the end-users, the public, and the Plaintiffs have instead been significantly damaged as a result of Defendants' respective actions.

786. ~~790.~~ Therefore, the Plaintiffs, therefore, seek disgorgement by each Defendant of all financial gains resulting from Defendant's respective wrongful conduct—to include,

disgorgement of all payments received from the end-users, the public, and the Plaintiffs.

K. Punitive Damages (All Defendants, excl. State Governmental Defendants).

787. ~~791.~~ Plaintiffs re-allege all paragraphs of this Complaint as if set forth fully herein. ~~792.~~788. By engaging in the above-described intentional and/or unlawful acts or practices,

Defendants acted with actual malice, wantonly, and oppressively. Defendants acted with conscious disregard to the rights of others and/or in a reckless, wanton, willful, or gross manner. Defendants acted with a prolonged indifference to the adverse consequences of their actions and/or omissions. Defendants acted with a conscious disregard for the rights and safety of others in a manner that had a great probability of causing substantial harm. Defendants acted toward the Plaintiffs with fraud, oppression, and/or malice.

789. ~~793.~~ Defendants were marketing, selling, distributing, and/or dispensing dangerous opioid drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in opioid drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the Commonwealth of Kentucky, these opioid drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence, and the safety of the public, making an award of punitive damages both appropriate and warranted—to serve as a punishment for Defendants’ greed and to serve as a future deterrent.

790. ~~794.~~ By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and exhibited a complete lack of care and concern thereby supporting a presumption of wanton and reckless indifference to the Plaintiffs.

791. ~~795.~~ Pursuant to KRS 411.184, Defendants’ collective and individual actions warrant

an award of punitive damages to the Plaintiffs—assessed against each Defendant—given there is clear and convincing evidence that each Defendant acted towards the Plaintiffs with oppression, fraud, and/or malice.

792. ~~796.~~ In addition to the litany of facts already discussed herein, each Defendant engaged in oppression by knowingly, wantonly, and willfully subjecting end-users, the public, and the Plaintiffs to cruel and unjust hardship. Defendants collectively and individually were fully aware of, and exploited for financial gain, the overwhelming risk of opioid addiction. The resulting addiction, and corresponding impact on Plaintiffs, was both cruel and unjust. The deaths, injuries, and destroyed families throughout the Plaintiffs' ~~communities~~ cities, while largely irreversible, are the product of each Defendant's greed.

793. ~~797.~~ Each Defendant knowingly, wantonly, and willfully committed fraud with respect to the end-users, the public, and the Plaintiffs. Defendants collectively and individually:

- made intentional misrepresentations concerning the risk of opioid use, as well as the necessity and efficacy of opioids for treating chronic pain; and
- concealed material facts from the end-users, the public, the Plaintiffs, and Kentucky regulators—facts that, if disclosed, could have significantly reduced or abated the opioid epidemic.

794. ~~798.~~ Each Defendant acted with malice towards the end-users, the public, and the Plaintiffs. Defendants collectively and individually acted with flagrant indifference to its legal obligations to the end-users, the public, and the Plaintiffs despite being fully aware that its actions would likely result in significant injuries (e.g. death, bodily harm, etc.).

795. ~~799.~~ Pursuant to KRS 411.186, the amount of the punitive damages warranted against each Defendant should consider each respective Defendant's respective:

- Defendant's clear knowledge of, and intentional and willful disregard, for the serious harm to the Plaintiffs that would arise from its

misconduct;

- Defendant's financial gains—profitability—resulting from its misconduct;
- Defendant's lengthy history of, and unrepentant and ongoing, misconduct; and
- Defendant's wholesale failure, and steadfast refusal, to remedy its known misconduct.

L. Writ of Mandamus (Kentucky Governmental Defendants).

796. ~~800.~~ Plaintiffs re-allege all paragraphs of this Complaint as if set forth fully herein. ~~801.~~ 797. Kentucky permits a party to seek a writ of mandamus to compel a governmental

official—the Kentucky Governmental Defendants—to perform and to carry out their required and non-discretionary duties.

798. ~~802.~~ Each of the Kentucky Governmental Defendants are subject to non-discretionary statutory duties and requirements to protect the public, including inter alia the Plaintiffs, from the unlicensed, fraudulent, and/or improper manufacture, marketing, distribution, sale, and dispensing of opioids—controlled substances—within and throughout the Commonwealth.

799. ~~803.~~ The Plaintiffs seek a writ of mandamus to require the Kentucky Governmental Defendants to fulfill their statutory duties.

M. Declaratory Relief (Kentucky Governmental Defendants).

800. ~~804.~~ Plaintiffs re-allege all paragraphs of this Complaint as if set forth fully herein. ~~805.~~ 801. The Plaintiffs are municipal entities wholly independent and separate from the

Commonwealth of Kentucky—entrusted with and expected to protect their constituents through

802. ~~806.~~ The Plaintiffs have suffered damages, and continue to be damaged, by the individual and collective actions of the Defendants that resulted in Kentucky's current and

ongoing Opioid Epidemic.

~~807.~~803. The Plaintiffs seek a declaration that the Kentucky Governmental Defendants are not empowered nor permitted to accept, negotiate, or interfere in any manner with the Plaintiffs' efforts and claims for relief from the Defendants.

804. ~~808.~~ The Plaintiffs seek a declaration that, in the event the Kentucky Governmental Defendants recover, obtain, receive, or collect any funds or any relief relating to or arising from the Plaintiff's claims and/or damages, the Kentucky Government Defendants shall immediately remit all said relief and funds to the Plaintiffs.

N. Injunctive Relief (Kentucky Governmental Defendants).

805. ~~809.~~ Plaintiffs re-allege all paragraphs of this Complaint as if set forth fully herein. ~~810.~~806. The Plaintiffs seek to enjoin the Kentucky Governmental Defendants from taking any action, or inaction, that will in any way adversely affect the Plaintiff's claims against and potential relief from the Defendants.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs respectfully prays that the Court grant the following relief:

~~811.~~807. The Court certify the Plaintiffs' claims as a Kentucky class action, name Plaintiffs as the Lead Class Plaintiffs, and appoint Plaintiff's undersigned counsel as Class Counsel.

A. Defendants.

808. ~~812.~~ Enter Judgment in favor of the Plaintiff Class, and against each Defendant, as to each and every claim asserted herein.

809. ~~813.~~ Enjoin each Defendant and its employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities,

subsidiaries, representatives, agents, and all other persons acting in concert or participation

with it, from

engaging in unfair or deceptive practices in violation of law and ordering temporary, preliminary or permanent injunction.

810. ~~814.~~ Enjoin each Defendant and its employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, representatives, agents, and all other persons acting in concert or participation with it, from violating and/or continuing to violate Kentucky laws and regulations relating to the manufacture, distribution, sale, and/or dispensing of opioids in the Commonwealth.

811. ~~815.~~ Revoke and/or suspend each Defendant's license to manufacture, distribute, sell, and/or dispense opioids in the Commonwealth of Kentucky. *See e.g., inter alia*, KRS 315.990(4), KRS 367.200.

812. ~~816.~~ Order each Defendant to remit all revenues received from the manufacture, distribution, sale, and/or dispensing of opioids in the Commonwealth of Kentucky during any period in which Defendant was not licensed by, and/or did not have a permit to operate from, the Kentucky Board of Pharmacy, with said revenues to include disgorgement of all related gains and profits.

813. ~~817.~~ Order each Defendant to pay the statutorily required fine of \$1,000 for each and every violation of KRS Chapter 315 occurring during the applicable period Defendant was subject to and doing business in the Commonwealth of Kentucky.

814. ~~818.~~ Order the Defendants to compensate the Plaintiff Class for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic.

815. ~~819.~~ Order the Defendants to fund an "abatement fund" for the purposes of abating the opioid public nuisance.

816. ~~820.~~ Award the Plaintiff Class, and order Defendants to pay, actual damages,

compensatory damages, special damages, injunctive and equitable relief, disgorgement, and forfeiture.

817. ~~821.~~ Award the Plaintiff Class, and order Defendants to pay, attorneys' fees and all costs and expenses, to include experts.

818. ~~822.~~ Award the Plaintiff Class, and order Defendants to pay, the consequential damages caused by the opioid epidemic (e.g. social, educational, treatment, employment, law enforcement, medical, and related services), including by way of example: (i) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (ii) costs for providing treatment, counseling, and rehabilitation services; (iii) costs for providing treatment of infants born with opioid-related medical conditions; (iv) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; and (v) costs associated with law enforcement and public safety.

819. ~~823.~~ Award the Plaintiff Class, and order Defendants to pay, punitive damages in the maximum amount permitted and in accordance with Kentucky law and due process.

820. ~~824.~~ Award the Plaintiff Class, and order Defendants to pay, pre-judgment and post-judgment interest.

821. ~~825.~~ Award the Plaintiff Class, and order Defendants to pay, all other relief as provided by law and/or as the Court deems appropriate and just.

B. State Governmental Defendants.

822. ~~826.~~ Enter Judgment in favor of the Plaintiff Class, and against the State Governmental Defendants, as to each and every claim asserted herein.

823. ~~827.~~ Award the Plaintiff Class, all available legal, equitable, declaratory, and

injunctive relief against the State Governmental Defendants.

824. ~~828.~~ Award the Plaintiff Class, and order the State Governmental Defendants to pay, attorneys' fees and all costs and expenses, to include experts.

825. ~~829.~~ Award the Plaintiff Class, and order the State Governmental Defendants to pay, pre-judgment and post-judgment interest where applicable.

826. ~~830.~~ Award the Plaintiff Class all other relief as provided by law and/or as the Court deems appropriate and just.

* * * * *

Dated: October 4, 2019

s/ Michael D. Grabhorn

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EXHIBIT 3

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
FRANKFORT DIVISION**

CITY OF HENDERSON, KENTUCKY, et al.,)	
)	
Plaintiffs,)	
)	
v.)	Case No. 3:19-cv-00067-GFVT
)	
PURDUE PHARMA, L.P., et al.)	Hon. Gregory F. VanTatenhove
)	
Defendants.)	JURY TRIAL DEMANDED

**DECLARATION OF SCOTT M. AHMAD IN SUPPORT OF DEFENDANT MCKESSON
CORP.'S OPPOSITION TO PLAINTIFFS' MOTION TO REMAND**

1. I am an attorney at the law firm Winston & Strawn, LLP, counsel for West-Ward Pharmaceuticals Corp. n/k/a Hikma Pharmaceuticals USA Inc. ("Hikma") in the above-captioned action. I have personal knowledge of the facts recited in this Declaration, and, if called upon to do so, I would competently and accurately testify under oath thereto. I make this Declaration in support of Defendant McKesson Corp.'s Opposition to Plaintiffs' Motion to Remand.
2. Contrary to Plaintiffs' assertion in its Motion to Remand that Hikma was served by certified mail prior to removal under the Kentucky Rules of Civil Procedure, Hikma was never properly served in this matter. Plaintiffs' attempted certified mail service was addressed generally to Hikma, but not to its authorized agent. This is insufficient under Kentucky law, and Hikma was thus not served.
3. Attached as Exhibit A is Hikma's forthcoming Motion to Quash Purported Service of Process.

4. If Hikma had been properly served, it would have nevertheless consented to removal of this case to federal court and does, in fact, consent to removal of this case.
5. I declare under penalty of perjury that the foregoing is true and correct.

Dated: November 18, 2019

Respectfully submitted,

/s/ Scott M. Ahmad

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EXHIBIT A

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
FRANKFORT DIVISION**

CITY OF HENDERSON, KENTUCKY, et al.,)	
)	
Plaintiffs,)	
)	
v.)	Case No. 3:19-cv-00067-GFVT
)	
PURDUE PHARMA, L.P., et al.)	Hon. Gregory F. VanTatenhove
)	
Defendants.)	JURY TRIAL DEMANDED

**DEFENDANT WEST-WARD PHARMACEUTICALS CORP.'S
MOTION TO QUASH PURPORTED SERVICE OF PROCESS**

Defendant West-Ward Pharmaceuticals Corp., n/k/a Hikma Pharmaceuticals USA Inc. (“Hikma”),¹ respectfully requests that this Court grant its Motion to Quash Purported Service of Process. This case was removed from Kentucky state court to this Court. Plaintiffs have contended that Hikma was properly served by certified mail prior to the removal under the Kentucky Rules of Civil Procedure.

Hikma, however, was not properly served. Under Kentucky law, service by certified mail has to be directed to a company’s authorized agent for service of process. Otherwise, the service is invalid. That is exactly the case here. Plaintiffs’ attempted certified mail service was addressed generally to Hikma, but not to its authorized agent for service of process. Therefore, Plaintiffs’ purported service of process must be quashed.

¹ Hikma files this Motion with full reservation of any and all defenses, objections, and exceptions, and without waiving service or its right to challenge personal jurisdiction.

BACKGROUND

1. On September 13, 2019, Plaintiffs filed an eleven-count Class Action Complaint against Hikma and 56 other defendants (the “Complaint”) in Franklin Circuit Court, Second Division, Commonwealth of Kentucky. *See* Pls.’ Compl., ECF. Nos. 1-2, 1-3, 1-4, 1-5, 1-6, 1-7, 1-8, and 1-9.

2. On or about September 23, 2019, Plaintiffs attempted to effect service of process upon Hikma by certified mail. *See* Pls.’ Mot. to Remand Decl. 1, ECF No. 85-3 (“Drake Declaration”); *see also* Pls.’ Mot. to Remand Ex. B., ECF No. 85-2 (“Summons and USPS Tracking Sheet”). However, although Plaintiffs apparently sent a copy of the Summons and Complaint to Hikma via certified mail, Plaintiffs failed to address the envelope to any officer, managing agent, or any other agent authorized to accept service on behalf of Hikma. Instead, Plaintiffs simply addressed it to “WEST WARD PHARMACEUTICALS CORP” at 246 Industrial Way West, Eatontown, NJ 07724. *See* Summons and USPS Tracking Sheet at 1, 4. On information and belief, Plaintiffs have made no other attempts to otherwise serve Hikma.

3. On October 24, 2019, Defendant McKesson Corporation (“McKesson”)—with the consent of all other Defendants who had been served as of that date—filed a Supplemental Notice of Removal. *See* Suppl. Notice of Removal, ECF No. 81. Hikma’s consent to removal was neither required nor given at the time of filing because—as further explained below—Hikma had not yet been properly served.

4. On October 28, 2019, Plaintiffs filed their Motion to Remand the Class Action Complaint to Franklin Circuit Court. *See* Pls.’ Mot. to Remand, ECF No. 85.

5. Among other reasons, Plaintiffs claim that McKesson's Supplemental Notice of Removal was deficient because McKesson failed to obtain unanimous consent from all Defendants who had been served as of the time of its filing. *See id.* at 9.

6. Namely, Plaintiffs assert that they served Hikma on September 23, 2019, and that McKesson improperly failed to obtain Hikma's consent to removal. *Id.*

7. However, Plaintiffs' purported service of process upon Hikma was insufficient, and Hikma therefore respectfully requests this Court to grant its Motion to Quash Purported Service of Process.

ARGUMENT

8. Plaintiffs contend that they properly effected service upon Hikma by sending a copy of the Summons and Complaint via certified mail addressed only to "WEST WARD PHARMACEUTICALS CORP" and delivered to its corporate home office at 246 Industrial Way West, Eatontown, NJ 07724. *See id.*; *see also* Drake Declaration at 1; Summons and USPS Tracking Sheet at 1, 4.

9. However, Plaintiffs are incorrect. Although service upon a corporation may occur through the use of certified mail in accordance with the Kentucky Rules of Civil Procedure,² *see* Ky. R. Civ. P. 4.01(1)(a), to satisfy the requirements of due process, the certified mail service must

² Because the attempted service in question occurred while the matter was still before the Franklin Circuit Court, this Court must apply the Kentucky Rules of Civil Procedure in determining whether the service of process was sufficient. *See Hertel v. Mortg. Elec. Registration Sys., Inc.*, No. 1:12-CV-174, 2012 WL 4754964, at *3 (W.D. Mich. Oct. 4, 2012) ("[I]n determining the validity of service in the state court *prior to removal*, a federal court must apply the law of the state.") (alteration in original) (citing 4A CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1082 (4th ed. 1998)); *see also United Steel Supply, LLC v. Butler*, No. 3:13-CV-00362-H, 2013 WL 3790913, at *2-4 (W.D. Ky. July 19, 2013) (applying Kentucky rules to govern the requirements for service of process because "Plaintiff attempted to effectuate service while the matter was before Kentucky courts" and prior to removal).

be specifically addressed to one of the individuals identified in Kentucky Rule of Civil Procedure 4.04(5)—*i.e.*, an officer or managing agent of the corporation, the chief agent of the corporation in the county wherein the action is brought, or any other agent of the corporation authorized to receive service on its behalf. *See Foremost Ins. Co. v. Whitaker*, 892 S.W.2d 607, 608-10 (Ky. Ct. App. 1995); Ky. R. Civ. P. 4.04(5) (“Service shall be made upon a corporation by serving an officer or managing agent thereof, or the chief agent in the county wherein the action is brought, or any other agent authorized by appointment or by law to receive service on its behalf.”). Consequently, if a plaintiff instead attempts to effectuate service upon a corporation via certified mail addressed only to the corporation in its corporate name, then the resulting service of process would be insufficient under the Kentucky Rules of Civil Procedure. *See Foremost Ins. Co.*, 892 S.W.2d at 609-10 (finding certified mail that was generally addressed to a company in its corporate name—rather than specifically to any of the company’s authorized agents—to constitute insufficient service of process).

10. In discussing the reasoning behind the requirement that certified mail be specifically addressed to a corporation’s authorized agent rather than generally to the corporation in its corporate name, Kentucky state courts have cited the following:

[T]he question might arise whether service on a corporation or other defendant which is not a natural person, might be had by merely addressing the certified envelope containing the process of the court to the home office of the corporation, rather than to a person specified in [Kentucky Rule of Civil Procedure] 4.04(5) [Kentucky Rule of Civil Procedure] 4.04(5) provides that ‘service shall be made upon a corporation by serving an officer or managing agent thereof.’ This means that the certified letter should be addressed to the officer or managing agent in the manner prescribed by [Kentucky Rule of Civil Procedure] 4.01. *If the interpretation were permitted that the corporation could be validly served by addressing the certified envelope merely in the corporate name to be delivered at the home office, there is too much risk that the process would not find its way into the hands of a responsible person.*

Foremost Ins. Co., 892 S.W.2d at 610 (first alteration in original) (citing WILLIAM O. BERTELSMAN & KURT A. PHILIPPS, JR., 6 KENTUCKY PRACTICE 34 (4th ed. 1984)).

11. Plaintiffs have plainly failed to effect sufficient service of process upon Hikma. Instead of specifically addressing the certified envelope containing the Summons and Complaint to an officer, managing agent, or any other agent authorized to accept service on behalf of Hikma, Plaintiffs improperly addressed the certified mail generally to “WEST WARD PHARMACEUTICALS CORP” at its corporate home office of 246 Industrial Way West, Eatontown, NJ 07724. *See* Summons and USPS Tracking Sheet at 1, 4; *see also* Drake Declaration at 1. Again, however, certified mail that is only addressed generally to a corporation in its corporate name—rather than specifically to an agent authorized to accept service on behalf of the corporation—does *not* constitute sufficient service of process under the Kentucky Rules of Civil Procedure. Thus, when Plaintiffs contend that they properly served Hikma on September 23, 2019, they are simply incorrect.

CONCLUSION

12. In light of Plaintiffs’ failure to serve Hikma in accordance with the Kentucky Rules of Civil Procedure, this Court should quash Plaintiffs’ purported service of process. An Order granting the relief requested is tendered with this Motion.

EXHIBIT 4

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION)	CASE NO.: 1:17-MD-02804
OPIATE LITIGATION)	
)	JUDGE DAN A. POLSTER
)	
)	MAGISTRATE JUDGE DAVID A. RUIZ
)	
)	
)	<u>STATEMENT OF INTEREST</u>
)	<u>OF THE UNITED STATES OF AMERICA</u>
)	
)	

STATEMENT OF INTEREST

Pursuant to 28 U.S.C. § 517, the United States respectfully submits this Statement of Interest to attend to its interests in connection with these actions.

INTRODUCTION

These consolidated actions seek damages from manufacturers and wholesale distributors of prescription opioids. The Complaints in each of these cases allege, generally, that defendants used false, deceptive, and unfair marketing and/or unlawful diversion of prescription opioids, which has resulted in a national epidemic of opioid overdose deaths and addictions. The plaintiffs in these actions include numerous cities, municipalities, and medical institutions that have borne the costs of the prescription opioid crisis. Plaintiffs seek to recover the costs associated with providing treatment and public safety measures relating to the opioid epidemic.

The United States submits this Statement of Interest to inform the Court of some of the substantial costs that the federal government has borne as a result of the opioid epidemic. In light of its substantial costs and significant interest in addressing the opioid epidemic, including significant public health and regulatory interests not discussed in this Statement, the United States

respectfully asks that the Court afford it a period of thirty days to evaluate whether to participate in these proceedings at this stage.

THE UNITED STATES' INTERESTS

On October 26, 2017, the President of the United States directed the Secretary of the Department of Health and Human Services to declare the opioid crisis a national public health emergency under federal law. *See* President's Commission on Combating Drug Addiction and the Opioid Crisis, *Chairman's Letter* at 5 (Nov. 2017). As the President has acknowledged, "the leading cause of unintentional deaths in the United States is now drug overdose deaths." *Id.* More than 175 Americans are dying every day from drug overdose. *Id.* Sadly, the opioid epidemic "actually lowered American life expectancy in 2015 and 2016 for the first time in decades." *See Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force* (Feb. 27, 2018), available at: <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-prescription-interdiction-litigation-task-force> ("PIL Task Force Announcement").

The federal government has deployed extensive efforts to combat the opioid epidemic. For example, in July, 2017, Attorney General Jeff Sessions announced charges against more than 120 defendants for crimes related to prescribing or distributing opioids and other dangerous narcotics. *See* PIL Task Force Announcement. Subsequently, the Department of Justice seized AlphaBay, the largest criminal marketplace on the Internet (which hosted some 220,000 drug listings). *Id.* In October, 2017, the DEA established six new enforcement teams focused on combatting the flow of heroin and illicit fentanyl into the U.S., based in communities facing some of the most significant challenges with these drugs. *Id.* The federal government is also continuing to assist state and local efforts to combat the crisis. For example, on September 22, 2017, the Attorney General announced that nearly \$20 million in federal grants would be awarded to help law

enforcement and public health agencies address prescription drug and opioid abuse. *See* Attorney General Jeff Sessions, Remarks by Attorney General Sessions to Law Enforcement About the Opioid Epidemic (Sept. 22, 2017). Continuing these many efforts, on February 27, 2018, Attorney General Sessions announced the appointment of an experienced federal prosecutor, Mary Daly, to serve as Director of Opioid Enforcement and Prevention Efforts. *See* Attorney General Sessions, Remarks (Feb. 27, 2018), available at: <https://www.justice.gov/opa/speech/attorney-general-sessions-delivers-remarks-announcing-prescription-interdiction-and>. The Attorney General also announced the creation of the Prescription Interdiction and Litigation Task Force to fight the prescription opioid epidemic. *See* PIL Task Force Announcement. Among its responsibilities, the PIL Task Force is “directed . . . to examine existing state and local government lawsuits against opioid manufacturers to determine what assistance, if any, federal law can provide in those lawsuits.” *Id.*

It is unsurprising that the federal government has borne substantial costs from the opioid epidemic. In 2013, the total economic burden associated with opioid overdose, abuse, and dependence was estimated to be \$78.5 billion. *See* President’s Commission on Combating Drug Addiction and the Opioid Crisis, *Health, Financial, and Social Consequences* at 31 (Nov. 2017). “Approximately 25% of the economic burden was borne by public sector (Medicaid, Medicare, and veterans’ programs) and other government sources for substance abuse treatment.” *Id.* In November 2017, the Council of Economic Advisors found that previous estimates of economic costs associated with the opioid crisis were “greatly understate[d].” *See* Council of Economic Advisors, Exec. Office of the President, *The Underestimated Costs of the Opioid Crisis* (Nov. 2017). The Council estimated that in 2015, the economic cost of the opioid crisis was \$504 billion, or 2.8 percent of the GDP that year. *Id.*

The economic burden from the opioid epidemic includes considerable costs associated with the medical treatment of opioid users. “Opioid users have higher numbers of [Emergency Department] visits, more inpatient hospital stays, along with almost double the inpatient costs compared to their non-opioid using counterparts.” President’s Commission on Combating Drug Addiction and the Opioid Crisis, *Health, Financial, and Social Consequences* at 30 (Nov. 2017). The United States’ various agencies provide treatment to, or provide payments for medical services on behalf of, patients who have used prescription opioids. And the costs of such treatment is significant. For example, the Department of Defense’s cost of care related to opioid use, abuse, and dependence was \$82 million in Calendar Year 2017.

FEDERAL RECOVERY STATUTES

Multiple federal statutes afford the United States the right to recover funds when the United States has paid for or provided treatment. Those statutes include, *inter alia*, (1) the Medicare Secondary Payer Act, 42 U.S.C. § 1395y, (2) the Federal Medical Care Recovery Act (“MCRA”), 42 U.S.C. §§ 2651-2653, and (3) the Veterans Benefits Act, 38 U.S.C. § 1729.

I. THE MEDICARE SECONDARY PAYER ACT

“Medicare is a federal entitlement program that provides health insurance benefits to qualified elderly and disabled individuals.” *Taransky v. Secretary of U.S. Dep’t of Health and Human Serv.*, 760 F.3d 307, 310 (3d Cir. 2014). Initially, “Medicare served as the primary payer of health costs for eligible individuals, but in 1980 Congress enacted the Medicare Secondary Payer Act to counteract escalating healthcare costs.” *Bio-Med. Applications of Tennessee, Inc. v. Cent. States Se. & Sw. Areas Health & Welfare Fund*, 656 F.3d 277, 281 (6th Cir. 2011). “To this end, when both Medicare and a private plan would cover a Medicare beneficiary’s expenses, the Act makes Medicare the ‘secondary’ payer and the private plan the ‘primary’ payer. The primary

payer is responsible for paying for the patient’s medical treatment; however, if Medicare expects that the primary payer will not pay promptly, then Medicare can make a ‘conditional payment’ on its behalf and later seek reimbursement.” *Id.* (citing 42 U.S.C. § 1395y(b)).

Under the Medicare Secondary Payer Act, Medicare payments are secondary and reimbursable “if it is demonstrated that [a] primary plan has or had a responsibility to make payment with respect to such item or service.” 42 U.S.C. § 1395y(b)(2)(B)(ii). A primary plan and any entity that receives payment from a primary plan, including a Medicare beneficiary that obtains a judgment against or settles with a primary plan, is responsible for reimbursing Medicare for conditional payments.

The Medicare Secondary Payer Act affords the United States a cause of action against a “primary plan” (or any entity that has received payment from a primary plan) to recover Medicare payments for items or services where the primary plan is responsible for that payment. This cause of action lies “against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan.” 42 U.S.C.

§ 1395y(b)(2)(B)(iii).¹

II. THE FEDERAL MEDICAL CARE RECOVERY ACT

The Federal Medical Care Recovery Act (“MCRA”), 42 U.S.C. §§ 2651-2653, “provides that when the United States furnishes medical care to a person who is injured under circumstances

¹ Under the cooperative federalism model of Medicaid, State Medicaid agencies are responsible for identifying third parties with primary liability for payment, and pursuing recovery from those primary payers. 42 U.S.C. § 1396a(a)(25)(A), (B). The federal government then shares in the recovery from a liable third party.

creating tort liability on a third party, the government may recover the value of medical services from the third party.” *Heusle v. National Mut. Ins. Co.*, 628 F.2d 833, 836 (3d Cir. 1980). “The operation of this statute in the context of a routine negligence case is relatively straightforward; the government simply stands in the position of a favored subrogee to the claim of an injured party against the tortfeasor.” *Id.* at 837. The MCRA “confers an independent right of action on the federal government, one that is not subject to a state’s statute of limitations, a state’s rules of interspousal immunity, or other procedural restrictions” *Id.* (internal citations omitted).

III. THE VETERANS BENEFITS ACT

“Federal law pertaining to veterans benefits places the United States on an equal footing with private hospitals in its attempts to recover from third parties the cost of medical services provided veterans for non-service-related injuries.” *United States v. Maryland*, 914 F.2d 551, 553 (4th Cir. 1990); *see also United States v. State of Ohio*, 957 F.2d 231, 232 (6th Cir. 1992). Section 1729 of Title 38, United States Code, is a no-fault statute and applies to health care plans, workers compensation plans, and no-fault insurance plans. 38 U.S.C. § 1729; *see also United States v. Blue Cross/Blue Shield of Alabama*, 999 F.2d 1542, 1544 n.2 (11th Cir. 1993) (“38 U.S.C. § 1729 provides that when a veteran is furnished medical services by the United States for a non-service-connected condition, the United States can recover the cost of such service under a health-plan contract if the veteran would be eligible to recover the cost had the services not been provided by the United States.”). “[S]ection 1729 proscribes any . . . discriminat[ion] in practice against VA facilities” relative to facilities not operated by the VA, and forbids the “law of any State” and the “provision[s] of any contract or other agreement” from “operat[ing] to prevent recovery or collection by the United States.” *United States v. Capital Blue Cross*, 992 F.2d 1270, 1272 (3d Cir. 1993); 38 U.S.C. § 1729(f). The United States may enforce its right to recovery under 38

U.S.C. § 1729 by electing subrogation, intervention, or by pursuing a separate action against the third-party payor in federal court, *see Maryland*, 914 F.2d 551, and “[t]his collection activity assists with the funding of VA medical care for veterans.” *Grant v. United States*, No. 11-cv-00360, 2012 WL 5289309, at *2 (E.D. Cal. Oct. 23, 2012).

OTHER LEGAL CONSIDERATIONS FOR THE UNITED STATES

In addition to the interests described above, the United States must consider its other law enforcement and legal activities in conjunction with any decision to engage with the multidistrict litigation. The broad scope of the United States’ activities is reflected in the Department’s many actions over the past year to help end the opioid crisis, as well as the ongoing responsibilities Attorney General Sessions has assigned to the PIL Task Force, including the coordination of:

- Criminal and civil remedies available under federal law to hold opioid manufacturers accountable for unlawful practices.
- Use of criminal and civil tools to crack down on pain-management clinics, drug testing facilities, and physicians that prescribe opioids.
- Criminal and civil tools available under the Controlled Substances Act against doctors, pharmacies, and others that break the law.
- Holding distributors such as pharmacies, pain management clinics, drug testing facilities, and individual physicians accountable for unlawful actions.
- Criminal and civil actions to ensure that distributors and pharmacies are obeying Drug Enforcement Administration rules designed to prevent diversion and improper prescribing.
- Interdiction of criminal marketplaces used for the distribution of opioids.

See PIL Task Force Announcement. Specific provisions of law under which the United States may accordingly act include, but are not limited to, anti-fraud statutes, 18 U.S.C. §§ 1341-1347, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, the Controlled Substances Act, 21 U.S.C.

§ 811, et seq., and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq. The United States does not believe that it would be proper to consolidate a possible action under one of these statutes with the actions in this multidistrict litigation.

CONCLUSION

The United States respectfully requests that this Court consider its interests as set forth above, and afford the United States a period of thirty days to evaluate whether to participate in these proceedings at this stage.

Respectfully submitted,

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Attorneys for the United States of America

EXHIBIT 5

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION)	
OPIATE LITIGATION)	MDL 2804
)	
THIS DOCUMENT RELATES TO:)	Case No. 1:17-md-2804
)	
<i>Commonwealth of Kentucky et al. v.</i>)	Judge Dan Aaron Polster
<i>Walgreens Boots Alliance, Inc. et al.,</i>)	
1:18-op-46311-DAP)	<u>ORDER</u>

On Monday, January 14, 2019, the Court entered an Opinion and Order on the Commonwealth of Kentucky's Motion to Remand. Doc. #: 13. Prior to that order issuing, Walgreens filed a Notice of Consent to Remand. Doc. #: 12.

Upon consideration of Defendant Walgreens' Notice of Consent to Remand, the Court hereby withdraws its previous Opinion and Order as moot and **ORDERS** that the action entitled Commonwealth of Kentucky et al. v. Walgreens Boots Alliance, Inc. et al., 1:18-op-46311 (E.D. Ky.) is **REMANDED** to the Boone Circuit Court, Division III, Boone County, Kentucky.

IT IS SO ORDERED.

/s/ Dan Aaron Polster January 17, 2019
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
AT FRANKFORT**

CITY OF HENDERSON, KENTUCKY, ON)	
BEHALF OF THEMSELVES AND ALL)	
OTHER SIMILARLY SITUATED HOME)	
RULE CITIES,)	
)	Civil Action No. 3:19-CV-00067-
Plaintiff,)	GFVT
)	
v.)	<i>Electronically Filed</i>
)	
PURDUE PHARMA L.P., et al.,)	
)	
Defendants.)	

ORDER DENYING PLAINTIFF'S MOTION TO REMAND

On motion by Plaintiff to remand, and the Court being sufficiently advised,

IT IS HEREBY ORDERED that Plaintiff's Motion to Remand (Dkt. No. 85) is DENIED.

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
FRANKFORT DIVISION**

**CITY OF HENDERSON, KENTUCKY,
ON BEHALF OF THEMSELVES AND
ALL OTHER SIMILARLY SITUATED
HOME RULE CITIES,**

PLAINTIFFS,

v.

PURDUE PHARMA L.P., ET AL.,

DEFENDANTS.

No. 3:19-cv-00067-GFVT

**REPLY IN FURTHER SUPPORT OF
PLAINTIFFS' MOTION TO REMAND**

TABLE OF CONTENTS

INTRODUCTION.....	1
DISCUSSION	2
A. Defendant McKesson has <i>not</i> established CAFA jurisdiction.	2
1. McKesson has <i>not</i> demonstrated, <i>nor</i> addressed, the amount in controversy.....	2
2. McKesson has <i>not</i> demonstrated the CAFA numerosity requirement is met.....	3
3. The Local Controversy exception warrants remand.	5
B. Defendant McKesson has <i>not</i> established federal question jurisdiction.	7
1. McKesson failed to obtain the required consent from all defendants.....	8
2. McKesson offers <i>no response</i> to the litany of cases in which the federal court’s found McKesson’s CSA jurisdictional arguments without merit... ..	9
3. McKesson offers <i>no rebuttal</i> to the persuasive authority of Judge Polster.	13
4. McKesson misstates the Supreme Court’s holding in <i>Merrell Dow</i> , which supports remanding the Home Rule City Class’ state law claims.	14
5. McKesson is <i>not</i> candid in its characterization of the Home Rule City Class’ claims.	15
CONCLUSION	15

INTRODUCTION

Despite Defendant McKesson Corp.’s (“McKesson”) lengthy protests and, to use its own prose, “sophistry,”¹ the Plaintiffs’ (the “Home Rule City Class”) claims must be remanded to state court. McKesson’s removal remains procedurally and substantively flawed.

With respect to CAFA, McKesson has *not* satisfied two of the statutory requirements: (i) the \$5 million amount in controversy; and (ii) the 100-minimum proposed class members. McKesson has *offered no proof* as to the amount in controversy. Further, McKesson concedes that the Home Rule City Class proposed members total *less than 100*. McKesson’s efforts to graft another lawsuit onto this one, so as to bolster the class size, are misplaced and not supported by the statutory text, the law, or the facts. Therefore, having failed to satisfy either, or both, of these statutory requirements, removal under CAFA was improper.

With respect to federal question, as a threshold issue, McKesson has failed to satisfy the unanimity procedural requirement. McKesson failed to obtain consent from all of the Kentucky defendants. McKesson’s arguments that the Commonwealth should be realigned are without merit. Moreover, McKesson has not argued that the other Kentucky defendants should be realigned. Having failed to obtain the required consent from all defendants, remand is required.

Even assuming McKesson had satisfied the statutory consent requirements, substantively its removal based on federal question jurisdiction also fails. Regardless of McKesson’s self-serving and selective characterization of the pleadings, the core of its argument is that the Home Rule City Class’ claims allege a violation of the CSA—a federal opioid reporting requirement that does not provide for a private cause of action. The Supreme Court has held that this sort of pleading does *not* rise to the level of a federal question.

We conclude that *a complaint alleging a violation of a federal statute* as

¹ Dkt. 107: McKesson Resp., p.6.

an element of a state cause of action, when Congress has determined that there should be ***no private, federal cause of action*** for the violation, does ***not*** state a claim “arising under the ... laws ... of the United States.”²

There is a “strong presumption” against removal. The removal statutes are to be ***narrowly*** construed. The removing party bears the burden of persuasion. Finally, ***any doubts*** are to be resolved in favor of remand.³ In light of the foregoing standard, remand is both warranted and required.

DISCUSSION

A. Defendant McKesson has ***not*** established CAFA jurisdiction.

As the Home Rule City Class noted in their motion to remand, in addition to a showing of minimal diversity,⁴ CAFA requires the removing party to also demonstrate: (i) greater than \$5,000,000 in controversy, and (ii) a proposed class size of at least 100 members.⁵ McKesson has not satisfied either of these remaining jurisdictional requirements.

1. McKesson has ***not*** demonstrated, ***nor*** addressed, the amount in controversy.

With respect to the amount in controversy, McKesson’s removal papers simply incorporated Sackler’s removal papers.⁶ Sackler’s papers simply concluded, without discussion, that “the amount in controversy based on Plaintiffs’ allegations exceeds \$5 million McKesson.”⁷ McKesson in turn has offered no evidence or facts to support this conclusory statement, instead

² *Merrell Dow Pharms. v. Thompson*, 478 U.S. 804, 817 (1986) (emph. added).

³ *Saint Paul Mercury Indem. Co. v. Red Cab Co.*, 303 U.S. 283, 290 (1938); *Long v. Bando Mfrg. of America, Inc.*, 201 F.3d 754, 757 (6th Cir. 2000) (“removal statutes are to be narrowly construed”); *Eastman v. Marine Mech. Corp.*, 438 F.3d 544, 550 (6th Cir. 2006) (“all doubts resolved in favor of remand”).

⁴ Whereas McKesson failed to allege the minimal diversity requirement in its removal papers, Sackler’s removal notice alleged she was a Connecticut citizen. *See* Dkt. 1, p.5.

⁵ 28 U.S.C. §1332(d)(2) and (5)(B).

⁶ Dkt. 82, p.18 (“McKesson expressly incorporates and adopts by reference the grounds for removal stated in the Notice of Removal of Beverly Sackler.”).

⁷ Dkt. 1, p.5.

stating that the Home Rule City Class only challenged the numerosity requirement.⁸ The argument ignores two key issues. **First**, the Home Rule City Class did raise the issue in their motion to remand noting that CAFA requires a showing of the amount in controversy. **Second**, McKesson—not the Home Rule City Class—bears the burden of demonstrating each jurisdictional requirement is met.⁹ McKesson must make some effort to meet its burden—conclusory statements incorporated by reference are insufficient.

[T]he Sixth Circuit has adopted a preponderance of the evidence test as the standard by which the defendant must demonstrate the requisite amount in controversy.... [A] defendant **must do more** than show the “amount in controversy ‘may’ or ‘could’ exceed the requirement.” The Sixth Circuit has since held that CAFA does **not** alter the burden or standard for removal.¹⁰

It is **not** the Court’s obligation, **nor** the Home Rule City Class, to make McKesson’s case.¹¹ Absent even a minimal effort to satisfy its evidentiary burden, McKesson “has not made a showing that the stakes in this case exceed the \$ 5,000,000 CAFA minimum.”¹² Having failed to make any effort to demonstrate the amount in controversy, remand is required.

2. McKesson has **not** demonstrated the CAFA numerosity requirement is met.

The statute is clear. CAFA jurisdiction only provides federal jurisdiction where the proposed class encompassed 100 or more members. McKesson does **not** dispute that the Home

⁸ Dkt. 107, p.6.

⁹ *Roberts v. Mars Petcare US, Inc.*, 874 F.3d 953, 955 (6th Cir. 2017) (emph. added in part) (“As always, the **removing** defendant **bears the burden** of establishing federal court jurisdiction.”).

¹⁰ *Glazer v. Whirlpool Corp.*, 2008 U.S. Dist. LEXIS 85798, at *4-5 (N.D. Ohio Oct. 6, 2008) (emph. added, internal cites omitted).

¹¹ *MERV Props., LLC v. Friedlander*, 2015 Bankr. LEXIS 1509, at *44-45 (Bankr. E.D. Ky. May 4, 2015) (“[I]t is not the Court’s responsibility to make the party’s case.”).

¹² *Pittman v. Chase Home Fin., LLC*, 2007 U.S. Dist. LEXIS 53859, at *9 (N.D. Ohio July 25, 2007).

Rule City Class is comprised of **less than** 100 members. On this basis, the CAFA numerosity requirement is **not** met and remand is required.

Undeterred, McKesson has reiterated Sackler's argument that because there is a separate lawsuit involving a wholly distinct and separate group of plaintiffs, the Court should add the two proposed classes together to satisfy the numerosity requirement. McKesson's argument is **not** supported by the statutory text—hence the noticeable absence of any citation by McKesson. Similarly, the argument is **not** supported by case law. To the contrary, the statutory text and the case law support the Home Rule City Class' rights to pursue their complaint and claims, without impediment from any other litigation—including being forced to aggregate their claims solely so that McKesson can seek refuge in the federal courts.

First, McKesson's strained argument ignores that the Home Rule City Class are the masters of their complaint. As such, the Home Rule City Class are free to plead their complaint in the manner of their choosing, including pleading so as to avoid federal jurisdiction should they choose to do so.

The rule makes the plaintiff the master of the claim; he or she may avoid federal jurisdiction by exclusive reliance on state law.¹³

CAFA does **not** alter this precedential rule.¹⁴ While CAFA indicated a court may consider whether a complaint was drafted to avoid federal jurisdiction, Congress **limited** this inquiry to the "discretionary exception."¹⁵ Congress did **not** incorporate this consideration into any other part of CAFA, including the numerosity requirement.¹⁶ Even so, there is no evidence the Home

¹³ *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 392 (1987).

¹⁴ *Smith v. Nationwide Prop. & Cas. Ins. Co.*, 505 F.3d 401, 407 (6th Cir. 2007)

¹⁵ 28 U.S.C. §1332(d)(3).

¹⁶ 28 U.S.C. §1332(d)(5) (expressly stating that section (3) does not apply to any class with less than 100 proposed members).

Rule City Class drafted their complaint to avoid CAFA jurisdiction. The proposed class includes Kentucky cities, except for those that had already sought relief in the MDL.

Second, McKesson’s reliance on *Freeman* is misplaced.¹⁷ To begin, *Freeman*’s holding was “**limited to** the situation where there is no colorable basis for dividing up the sought-for retrospective relief into separate time periods, other than to frustrate CAFA.”¹⁸ Moreover, *Freeman* expressly held that “plaintiffs can avoid removal under CAFA by limiting the damages they seek to amounts less than the CAFA thresholds.”¹⁹ Unlike *Freeman*, the Home Rule City Class have **not** splintered their claims, their damages, or their time periods. The Home Rule City Class instead have asserted **all of** their state law claims, seeking **all of the** available relief unique to them, and against **all** defendants. Succinctly stated, the proposed city class was “not artificially split ... into multiple suits to avoid federal jurisdiction.”²⁰ McKesson’s argument that the Home Rule City Class **could** have combined their lawsuits with that of the Ky County Class is misplaced. CAFA does **not** operate in the context of speculation. Again, as already noted, CAFA does **not** alter the legal premise that the Home Rule City Class are the masters of their complaint. McKesson has **not** demonstrated the high threshold—“no colorable basis”—necessary for *Freeman* to apply.

3. The Local Controversy exception warrants remand.

With the sole exception of the “significant basis” element, McKesson concedes that all of the elements of the Local Controversy exception are present.²¹ In support of its opposition, McKesson summarily states that the complaint “barely mentions CVS Pharmacy and Rite Aid

¹⁷ *Freeman v. Blue Ridge Paper Prods.*, 551 F.3d 405 (6th Cir. 2008).

¹⁸ *Id.* at 409.

¹⁹ *Id.*

²⁰ *Grimsdale v. Kash N' Karry Food Stores, Inc.*, 564 F.3d 75, 79-80 (1st Cir. 2009).

²¹ Dkt. 107, pp.7-8.

Ky.”²² McKesson further complains that the Home Rule City Class did not plead “how many opioids” were dispensed and did not compare “the conduct of other retail pharmacies.”²³ Suffice to say, McKesson’s arguments and characterizations of the pleadings are misleading.

First, McKesson ignores the fact that Kentucky is a notice pleading state. Kentucky does not require a party to plead every know fact, just sufficient facts for a defendant to be aware of the nature of the claims. McKesson cannot seriously dispute that the Home Rule City Class went above and beyond in their detailed pleadings. Even so, the pleadings also clearly put McKesson on notice that “the factual allegations... are *not exhaustive*.”²⁴

Second, McKesson overlooks detailed pleadings concerning the Retail Pharmacy Defendants and their respective actions in Kentucky. Contrary to McKesson’s representation, the pleadings contained multiple factual allegations and claims concerning the Retail Pharmacy Defendants—including CVS Pharmacy and Rite Aid Ky. Of the six pharmacies operating in Kentucky—the gatekeeper to the dispensing of opioids to the public—CVS Pharmacy and Rite Aid Ky were two of the largest.²⁵ To say that two of the largest pharmacy companies in Kentucky, again entrusted with the dispensing of opioid medication, are not a significant part of the opioid epidemic is disingenuous at best. There is little doubt the Home Rule City Class has alleged that CVS Pharmacy’s and Rite Aid Ky’s respective conduct forms a “significant basis” of the claims.

²² *Id.*, p.8.

²³ *Id.*

²⁴ Dkt. 1-1, p.1 (emph. original).

²⁵ *Id.*, p.123 (“CVS is one of the largest companies in the world, with annual revenue of more than \$150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. As such, CVS was and remains uniquely positioned to serve as a gatekeeper to step the diversion and abuse of opioids.”); p.127 (“With approximately 4,600 stores ... Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States, with annual revenue of more than \$21 billion.”).

The allegations that LAN, P.C. was responsible for quality control, in conjunction with the allegation that defendants' engineering work in Flint was conducted "through LAN P.C." are sufficient to establish that LAN, P.C.'s conduct forms a "significant basis" of plaintiffs' professional negligence claim.²⁶

Similarly, the complaint's factual allegations provide a detailed comparison of all defendants' conduct, including CVS Pharmacy and Rite Aid Ky—again, two of the largest retail pharmacies. Where, as here, the local defendants' "alleged conduct is a significant part of the alleged conduct of all the Defendants, then the *significant basis provision is satisfied*."²⁷

B. Defendant McKesson has *not* established federal question jurisdiction.

McKesson cannot deny that the Home Rule City Class expressly stated they are *not* asserting any federal claims and further *disavowed* any such inference.

This action is *not* removable to federal court for many reasons, including inter alia ... (ii) the claims asserted herein arise solely under Kentucky's laws and regulations; (iii) *no claims are asserted under any federal law or regulation*, and any inference to the contrary is *expressly disavowed*...²⁸

The Home Rule City Class have asserted claims for *violation of Kentucky law* and, as such, seek relief provided by *Kentucky law*. McKesson's response largely ignores this key fact. Instead, based on a less than candid characterization of the complaint and the case law, McKesson contends that the Home Rule City Class' "claims" are somehow subsumed by federal law. The problem with McKesson's argument is, however, that federal question jurisdiction is not created by a fact, but rather by a claim. Moreover, even if a federal issue was raised in the Home Rule City Class' state law claims, at best they would only be as a defense by McKesson which is inadequate to confer federal jurisdiction.²⁹ As the federal courts have repeatedly held,

²⁶ *Mason v. Lockwood, Andrews & Newnam, P.C.*, 842 F.3d 383, 396-97 (6th Cir. 2016).

²⁷ *Powell v. Tosh*, 2009 U.S. Dist. LEXIS 98564, at *17 (W.D. Ky. Oct. 21, 2009) (emph. added).

²⁸ Dkt 1-1: Complaint, p.10 (emph. added).

²⁹ *Merrell Dow Pharms.*, 478 U.S. at 808 ("A defense that raises a federal question is

McKesson's arguments are without merit.

1. McKesson failed to obtain the required consent from all defendants.

McKesson readily concedes it did **not** obtain consent from all of the defendants—specifically the Kentucky entities.³⁰ The consent—unanimity—rule is **not** an option. Consent from **all defendants** is mandatory.³¹ The Kentucky entities have **not** consented and, in fact, have opposed this Court's jurisdiction.³² McKesson's "[f]ailure to obtain unanimous consent forecloses the opportunity for removal under Section 1446."³³

Undeterred, McKesson insists it was not required to obtain consent from the Kentucky defendants.³⁴ McKesson has **not** argued the Kentucky entities were fraudulently joined. Instead, McKesson insists the Kentucky defendants should be "aligned" with the Home Rule City Class.³⁵ McKesson's arguments are both factually and legally flawed. **First**, McKesson insists that the "Commonwealth" has asserted "claims nearly identical" to those of the Home Rule City Class.³⁶ However, McKesson **provides no evidence** to support this contention. McKesson does not provide the Commonwealth's complaint, nor does it provide a summary of the specific claims. This is woefully insufficient to support its "alignment" argument. Further, McKesson glosses over a key fact that wholly undermines its argument—there is no evidence the other Kentucky defendants have asserted any claims against it. The Kentucky defendants also include

inadequate to confer federal jurisdiction.").

³⁰ McKesson also did **not** obtain the consent of Defendant West-Ward who, despite their representations, were served on September 23, 2019—requiring any consent to removal to occur no later than October 23, 2019, which did not occur. However, given the Kentucky entities did **not** consent, West-Ward's objections are largely irrelevant to the remand.

³¹ 28 U.S.C. §1446(b)(2)(A) ("all defendants ... **must** ... consent to the removal") (emph. added).

³² Dkt. 110.

³³ *Loftis v. UPS*, 342 F.3d 509, 516 (6th Cir. 2003).

³⁴ Dkt. 107, pp.10-11.

³⁵ *Id.*

³⁶ *Id.*, p.11.

the Kentucky Pharmacy Board and the Cabinet for Health and Family Services.

Second, McKesson does not offer any discussion as to how the Home Rule City Class' claims ultimately differ amongst the defendants including the Kentucky defendants. Certainly, the Home Rule City Class have not asserted the same "claim" against the Kentucky defendants. But that applies as well to the other defendants. The fact remains, however, that all of the claims ultimately seek relief—from whatever source—for the damages incurred as the result of the opioid epidemic. Simply because one of the Kentucky defendants might be asserting similar claims does not mean it is seeking the same relief—nor could it. The damages incurred by the Home Rule City Class are unique to the respective counties wholly apart, and distinct, from the Kentucky defendants. At best, any "realignment" of the Commonwealth would be solely to add a designation of "counter-claim" plaintiff. The Commonwealth, as with the other Kentucky defendants, would remain a defendant for the Home Rule City Class' primary dispute—all defendants' individual and collective liability for the manufacture, marketing, distribution, sale and dispensing of opioids in Kentucky.

Section 1446's text controls. "The statute refers to civil actions, not claims."³⁷ There is no statutory proviso for separating claims so as to reclassify a defendant. One is either a defendant to the action, or not. McKesson does not, and cannot, dispute that the Kentucky defendants are just that—defendants in this action. Therefore, unless all defendants to the "action" consent, removal is improper, and remand is required.

2. McKesson offers *no response* to the litany of cases in which the federal court's found McKesson's CSA jurisdictional arguments without merit.

McKesson offers no response to the multiple cases cited by the Home Rule City Class in

³⁷ *Home Depot U.S.A., Inc. v. Jackson*, 139 S. Ct. 1743, 1748 (2019).

which McKesson's federal question arguments based on the CSA have been *rejected*.³⁸ Nor can it. The repeated rejection of McKesson's CSA arguments has moved beyond the mere persuasive authority of a potential outlier single court decisions. But that is not the case here. There has been a wave of court decisions—each consistently rejecting McKesson's CSA arguments. At some point, McKesson's "good faith" efforts to obtain a different outcome must give way to an abuse of the judicial process that only results in wasting limited resources and in unduly delaying resolution of the merits.

Turning back to the decisions rejecting McKesson's flawed CSA argument, the following excerpts are instructive:

- *Weber Cnty. v. Purdue Pharma, L.P.*, 2018 U.S. Dist. LEXIS 133312, at *2-3 (D. Utah Aug. 7, 2018) ("McKesson ... recently removed the case, arguing this court has federal question subject matter jurisdiction [based on CSA]...").

[E]ven if Weber County relied only on a breach of the federal CSA for a given state law claim ... the court likely still would *not find* the presence of a substantial issue of federal law. Doing otherwise, as McKesson urges, **would seemingly flout *Merrell Dow*, in which the Supreme Court found no federal subject matter jurisdiction under analogous facts** where plaintiffs directly claimed the defendant's alleged breach of a federal drug labeling statute established the defendant had been negligent per se and that negligence was the proximate cause of the injuries alleged in the consolidated cases. **As with the CSA, the federal statute at issue in *Merrell Dow* provided no private right of action. If federal question subject matter jurisdiction was lacking there, it is certainly not established here,** where Weber County does not expressly rely on the CSA in stating its claims and has offers in its papers that its claims are not directly based on the CSA.³⁹

That the complaint factually states the defendants failed to comply with the CSA is

³⁸ McKesson does cite, without discussion, four cases that allegedly support its argument. See Dkt. 107, p.22. However, none of the cases are available electronically and McKesson failed to attach them to its response—in violation of L.R. 7.1(h). As such, the citations should not be considered by the Court.

³⁹ *Id.* at *15 (emph. added); *see also, Uintah Cnty. v. Purdue Pharma, L.P.*, 2018 U.S. Dist. LEXIS 133310, at *24 (D. Utah Aug. 7, 2018) (same).

insufficient to warp the state law claims into a federal question, thereby usurping the sovereignty of the Kentucky state courts. Given Kentucky’s detailed and reticulated statutory and regulatory provisions concerning the manufacturer, marketing, distribution, sale, and dispensing of opioids,⁴⁰ defendants’ CSA failures only serves as further evidence of a wrongful pattern of conduct—it is *not* necessary to the Kentucky claims or proof thereof.

- ***City of Reno v. Purdue Pharma, L.P.***, 2018 U.S. Dist. LEXIS 187821, at *8-9 (D. Nev. Nov. 2, 2018) (“McKesson Corporation—removed based on federal question jurisdiction, alleging that Reno’s claims arise under federal law [based on CSA].”).

The *first factor weighs against* federal question jurisdiction because the CSA does *not* provide for a federal cause of action.

* * * * *

The *second factor also weighs against* federal question jurisdiction. ... McKesson has not persuaded this Court that the state court will have to make any inquiry regarding the scope and existence of the duties imposed by the CSA because *Reno could prevail on its claims based on the duties imposed by NAC § 453.400 alone....*

* * * * *

The *third factor*—whether the issue will have a broad impact on the federal system as a whole—also is not satisfied here. *The issue before the state court will be whether McKesson and others breached the duties imposed by Nevada law, including NAC § 453.400.*⁴¹

The court applied a similar analysis and again concluded that McKesson’s CSA jurisdictional claim could *not* serve as a basis to exercise federal question jurisdiction. The fact that the CSA does not provide for a private cause of action—even if pleaded—defeats any

⁴⁰ See e.g. KRS 218A Controlled Substances, KRS 315 Pharmacists and Pharmacies, 201 KAR Chapter 2, and 902 KAR Chapter 55.

⁴¹ *Id.* at *8-9 (emph. added, internal citations omitted); see also, *N.M. ex rel. Balderas v. Purdue Pharma L.P.*, 323 F.Supp.3d 1242, 1253 (D.N.M. 2018) (finding federal question jurisdiction did not apply); *Cnty. of Kern v. Purdue Pharma L.P.*, 2019 U.S. Dist. LEXIS 122709, at *7-8 (E.D. Cal. July 23, 2019); *City of Worcester v. Purdue Pharma Ltd. P’ship*, 2018 U.S. Dist. LEXIS 215824, at *10 (D. Mass. Nov. 21, 2018) (collecting cases).

removal efforts. For federal jurisdiction to apply, a party must have been able to bring the claim in federal court in the first instance—a legal impossibility. Furthermore, as the court recognized, the issues and interests are solely whether McKesson breached its duties *under state law*—as the Home Rule City Class has alleged.

- *Dunaway v. Purdue Pharma L.P.*, 391 F.Supp.3d 802, 806 (M.D. Tenn. 2019) (“McKesson asserted that, although the plaintiffs have pleaded only state-law causes of action, their claims ‘arise under federal law’ for jurisdictional purposes because they involve duties under the [CSA]”).

McKesson argues that the state-law grounds for finding liability under the TDDLA are insufficient because none of the cited provisions specifically includes a duty to report and refuse to fill “suspicious orders.” *The precise boundaries of the cited Tennessee law, however, present an issue of merits, not jurisdiction....* McKesson’s argument relies, unconvincingly, entirely on the lack of specific language about “suspicious” orders in the relevant Tennessee statutes. *Those statutes, however, merely reach the same issue from a different direction.* Tennessee law specifically prohibits the distribution of opioid medications for improper purposes....

Numerous other opioid-related cases involving purely state-law prohibitions have been remanded for similar reasons As those courts have recognized, the fact that opioid abuse is an issue of national importance that is addressed, to some degree, by federal law *in no way undermines the power of states to craft independent responses* that do not rely on federal law to impose liability. When a state has done so—as Tennessee has done here (by the plaintiffs’ theory of the case)—then *the appropriate forum for such causes of action are state courts*, unless a filing or removing party can establish a recognized basis for federal jurisdiction. Because *McKesson has not done so*, this court will remand the case.⁴²

McKesson cannot dispute that the Home Rule City Class has asserted their claims under state law—including inter alia Kentucky’s Controlled Substances Act and Pharmacists & Pharmacies Act.⁴³ Yet, McKesson inexplicably does *not* offer any discussion of the actual statutes and how they would interplay with any CSA factual allegations—let alone how CSA

⁴² *Id.* at 813-14 (emph. added) (collecting cases).

⁴³ KRS 218A and 315 respectively.

would trump Kentucky’s statutory, regulatory, and common law. McKesson does not even cite either of Kentucky’s opioid related statutes. It certainly cannot claim it was unaware of the need to do so given the Tennessee District Court’s recent—this year—rejection of McKesson’s efforts to contort Tennessee’s similar opioid laws. *See supra*. Having failed to provide any explanation of Kentucky’s laws—which do provide a private right of action—McKesson cannot meet its high burden of proof necessary to establish federal question jurisdiction.

3. McKesson offers *no rebuttal* to the persuasive authority of Judge Polster.

In addition to the federal courts’ consistent rejection of McKesson’s CSA jurisdictional argument, the very court—to which McKesson desperately seeks to transfer this case—has rejected the same argument advanced by another defendant.⁴⁴ McKesson offers no rebuttal to Judge Polster, in charge of the MDL, who expressly held that:

While a determination of a duty and violation of that duty under the [CSA] will likely occur in examining Plaintiff’s claims, so also will examination of [state] common law, statutes, and promulgated rules to determine Defendants’ duty, if any, to prevent “diversion” of prescription [T]o the extent ... Plaintiff’s claims are “partially predicated on federal law, ***federal law would still not be necessarily raised.***”⁴⁵

Instead, McKesson’s response simply notes Judge Polster entered a subsequent replacement order because Walgreens’ withdrew its opposition to remand.⁴⁶ On that basis, McKesson contends Judge Polster’s opinions and thoughts on the issue are not entitled to any deference—citing to an appellate criminal case involving vacatur as part of a settlement.⁴⁷ The cited case is inapposite. The issue here concerns a district court, ***not*** appellate. The order was ***not*** set aside based on a settlement. It was set aside because the defendant withdrew its opposition to remand.

⁴⁴ *In re Nat’l Prescription Opiate Litig.*, 2019 U.S. Dist. LEXIS 6425, at *65-66 (N.D. Ohio Jan. 14, 2019)

⁴⁵ *Id.* at *65-66 (emph. added) (also collecting cases).

⁴⁶ Dkt. 107, p.21.

⁴⁷ Citing *U.S. v. Sigma Int’l, Inc.*, 300 F.3d 1278 (11th Cir. 2002).

There is nothing that would indicate Judge Polster had suddenly changed his analysis or conclusion. “A logical and well-reasoned decision, despite vacatur, is *always persuasive authority*, regardless of its district of origin or its ability to bind.”⁴⁸

4. McKesson misstates the Supreme Court’s holding in *Merrell Dow*, which supports remanding the Home Rule City Class’ state law claims.

McKesson provides a highly selective snippet from the U.S. Supreme Court’s holding in *Merrell Dow*⁴⁹ to support its CSA jurisdictional arguments.⁵⁰ McKesson mischaracterizes the holding as being a hard and fast rule—stating “federal question jurisdiction exists if...”⁵¹ This was not the holding. To the contrary, *Merrell Dow* stated that “a case *may* arise under federal law.”⁵² It was *not* the absolute McKesson claims. Furthermore, McKesson omitted the warning from the Supreme Court that the statement “be read with caution” given the “central issue ... turned on the meaning of [ERISA].”⁵³

Furthermore, as multiple district courts have recognized, *see supra*, *Merrell Dow* actually supports remand. *Merrell Dow* directly addressed a *similar fact pattern* in the context of federal question jurisdiction. The plaintiff had alleged state law claims based on the defendant’s violation of Federal Food, Drug, and Cosmetic Act for misbranding. The Supreme Court concluded this was insufficient to support federal question jurisdiction.

[A] complaint alleging a violation of a federal statute as an element of a state cause of action, when Congress has determined that there should be ***no private, federal cause of action*** for the violation, does ***not*** state a claim “arising under the Constitution, laws, or treaties of the United States.”⁵⁴

⁴⁸ *Gutter v. E.I. DuPont de Nemours & Co.*, 2001 U.S. Dist. LEXIS 9701, at *18-19 (S.D. Fla. Mar. 26, 2001) (emph. added).

⁴⁹ *Merrell Dow Pharm., Inc. v. Thompson*, 478 U.S. 804 (1986).

⁵⁰ Dkt. 107, p.13.

⁵¹ *Id.*

⁵² *Merrell Dow Pharm., Inc.*, 478 U.S. at 808 (emph. added).

⁵³ *Id.* at 809.

⁵⁴ *Id.* at 817 (emph. added).

The Home Rule City Class’ claims are no different. While they allege facts concerning the CSA, they do not assert a federal claim—nor could they. The CSA does **not** provide for a private cause of action and, as such, cannot serve as grounds for federal question jurisdiction.

5. McKesson is *not* candid in its characterization of the Home Rule City Class’ claims.

Finally, McKesson’s response takes great liberty in its characterization of the Home Rule City Class’ claims—belying a less than candid representation to the Court. **First**, McKesson states that “Plaintiffs’ sole theory of unlawful conduct is that Distributors failed to report and refuse suspicious orders.”⁵⁵ As evidenced in the complaint, McKesson’s statement is inaccurate and misleading. The Home Rule City Class has alleged multiple theories against the defendants, including McKesson—all under Kentucky law.⁵⁶ **Second**, McKesson states that “Plaintiffs rely exclusively on alleged violations of the federal CSA, and do not specifically cite independent state-law.”⁵⁷ This statement is similarly inaccurate and misleading. The Home Rule City Class has specifically asserted statutory violations on the part of McKesson including *inter alia* KRS 218A, KRS 315, KRS 367, and 517.030. Contrary to McKesson’s protests, the Home Rule City Class has clearly stated state law claims based in part on multiple legal theories each of which is supported by Kentucky statutory, regulatory, and common law.

CONCLUSION

Based on the foregoing and as detailed in the Motion to Remand, Plaintiffs, on behalf of themselves and the Putative Class, respectfully request the Court grant their motion and remand their complaint to Kentucky State Court.

* * * * *

⁵⁵ Dkt. 107, p.15.

⁵⁶ Dkt.1-1: Complaint, ¶¶ 664-744; ¶¶752-789.

⁵⁷ Dkt. 107, p.21.

Dated: November 22, 2019

s/ Michael D. Grabhorn

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